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Contract No. DAMD17-79-C-9161
IITRI Project No. L6121
Study No. 6

DETERMINATION OF THE CHRONIC MAMMALIAN TOXICOLOGICAL EFFECTS OF RDX

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

PHASE V FINAL REPORT
Volume 3

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The findings in this report are not to be construed as an official Department of the Army position unless so designated by other authorized documents.

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APPENDIX XI

PATHOLOGY REPORT

The following synopsis of the over-all pathology report the this study is constructed from the detailed pathology reports and tables which occur in Volume III in the following order: (1) The Consulting Pathologist's Six Month Interim Report preceeded by tabulations of Gross findings; (2) The Corresponding Twelve Month Interim Report in the same order, and; (3) The Final Pathology Report (with Addendum).

PATHOLOGY REPORT

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

Necropsy Observations

No compound-related gross pathologic lesions were observed in Fischer 344 rats from the experimental groups sacrificed after six months on the study, rats that died during this period or those sacrificed *in extremis*.

Compound-related gross pathologic lesions were observed in male Fischer 344 rats from the experimental groups sacrificed after twelve months on the study, rats that died during this study period, or those sacrificed *in extremis*. Male rats at the 40.0 mg/kg/day dose level had red-brown fluid in the abdominal cavity, dark brown kidneys with renal pelvis dilatation, distended urinary bladder that contained dark-red fluid, small testes, enlarged red-brown seminal vesicles, and enlarged prostate distended with red-brown fluid. Enlarged dark-red spleen observed at necropsy for the 40.0 mg/kg/day dose level in male and female rats was also considered to be compound-related.

Compound-related gross pathologic lesions were observed in Fischer 344 rats from the experimental groups sacrificed at twenty-four months on the study, rats that died during this period, or those sacrificed *in extremis*. Male rats at the 40.0 mg/kg/day dose level had dark-brown, enlarged kidneys; enlarged, dark-red seminal vesicles; enlarged, dark-red prostate and distended urinary bladder. Compound-related lesions observed at necropsy in female rats at the 40.0 mg/kg/day dose level were white, opaque and small eyes.

Microscopic Observations

Treatment-related lesions observed microscopically in six month interim sacrificed males consisted of the following. There was a treatment-related increase of extramedullary hematopoiesis in the spleen of interim sacrificed (6/10) and spontaneous death and moribund sacrificed (2/5) males from the RDX 40.0 mg/kg/day group. Lesions of unilateral testicular degeneration were present among 3/10 interim sacrificed males in the RDX 40.0 mg/kg/day group. This change was accompanied by spermatic granulomas in the epididymis of two of these animals. There was also a significant increase of spermatic granulomas involving the coagulating gland (recorded under prostate) of interim sacrificed (6/10) and spontaneous death and moribund sacrificed (2/5) males of the RDX 40.0 mg/kg/day group when compared with the incidence among males of the RDX 0.0 mg/kg/day, RDX 0.3 mg/kg/day, and RDX 1.5 mg/kg/day groups. The no-effect level of RDX in males was

8.0 mg/kg/day. In six month interim sacrificed females there was a treatment-related increase of extramedullary hematopoiesis in the spleen of interim sacrificed females. The incidence in the RDX 40.0 mg/kg/day group was 5/10. The no-effect level of RDX in females was 8.0 mg/kg/day.

Treatment-related lesions observed microscopically in twelve month interim sacrificed males consisted of the following. Sinusoidal congestion was present in the spleen of all (10/10) interim sacrificed males in the RDX 40.0 mg/kg/day group. Lesions of unilateral or bilateral testicular degeneration were present among interim sacrificed (4/10) and spontaneous death and moribund sacrificed (4/19) males in the RDX 40.0 mg/kg/day group. Urogenital tract lesions consisting of necrosis of the renal medullary papilla (15/19), luminal distention of the urinary bladder (18/19), and hemorrhagic cystitis (17/19) were confined to spontaneous death and moribund sacrificed males in the RDX 40.0 mg/kg/day group. There was also diffuse parathyroid hyperplasia in 13/19 of these males. These lesions were accompanied by widespread parenchymal mineralization of visceral organs. These latter changes were regarded as a sequela to the renal injury. The no-effect level of RDX in males was 8.0 mg/kg/day. In twelve month interim sacrificed females a treatment-related diffuse sinusoidal congestion was present in the spleen of interim sacrificed (9/10) and spontaneous death and moribund sacrificed (1/17) females in the RDX 40.0 mg/kg/day group. The no-effect of RDX in females was 8.0 mg/kg/day.

Treatment-related lesions observed microscopically at twenty-four month terminal sacrifice follow. A dose-related increase of hemosiderin-like pigment was observed in the spleen of terminal sacrificed and spontaneous death and moribund sacrificed males in the RDX 1.5 mg/kg/day, RDX 8.0 mg/kg/day, and RDX 40.0 mg/kg/day groups. Treatment-related inflammatory-obstructive urogenital lesions, similar to those observed at the twelve month sacrifice period in RDX 40.0 mg/kg/day spontaneous death and moribund sacrifice animals were also present among a large number of spontaneous death and moribund sacrificed animals of the same dose level from the final study interval. Concurrent renal necrosis, bladder distention and cystitis occurred in one RDX 0.3 mg/kg/day spontaneous death and moribund sacrificed male. The changes in this male were of comparable severity to those observed among the RDX 40.0 mg/kg/day males from the same study interval. In addition, there were a few spontaneous death and moribund sacrificed males in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups with lesions of bladder distention and/or cystitis similar to those observed among the RDX 40.0 mg/kg/day group. Secondary lesions of parathyroid hyperplasia with uremic mineralization of visceral organs were observed in RDX 40.0 mg/kg/day spontaneous death and moribund sacrificed animals with treatment-related urogenital lesions. In view of the above observations, a no-effect level of RDX was not determined under the conditions of this study. In twenty-four month terminal sacrificed females there was a treatment-related increase in the incidence of lenticular cataracts involving one or both eyes in spontaneous death and moribund sacrificed females in the 40.0 mg/kg/day group. The no-effect level of RDX in females was 8.0 mg/kg/day.

Statistical Evaluation

Six month interim sacrifice: Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) lesions of extramedullary hematopoiesis in male and female rats at the 40.0 mg/kg/day dose level, when compared to the control group. Also statistically significant (at $p<0.05$) was the lesion of spermatic granuloma of the prostate in male rats at the 40.0 mg/kg/day dose level.

Twelve month interim sacrifice: Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) lesions of sinusoidal congestion of the spleen at the 40.0 mg/kg/day dose level in male and female rats. Statistically significant (at $p<0.05$) testicular germinal cell degeneration, kidney medullary papillary necrosis, luminal distention of the urinary bladder, with hemorrhagic and/or suppurative cystitis at the 40.0 mg/kg/day dose level in male rats were also observed during this study period.

Twenty-four month terminal sacrifice: Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) increased pigment in the spleen and suppurative inflammation of the prostate at the 1.5 mg/kg/day, 8.0 mg/kg/day and 40.0 mg/kg/day dose levels in male rats. Kidneys, medullary papillary necrosis, pyelitis, urinary bladder lumenal distention, cystitis in male rats at the 40.0 mg/kg/day dose level were statistically significant (at $p<0.05$) when compared to the control group.

In female rats at the 40.0 mg/kg/day dose level lenticular cataracts were statistically significant (at $p<0.05$).

All other lesions observed microscopically which were submitted for statistical analysis were not significantly different from the control group in male and female rats that either died, were sacrificed *in extremis*, or were sacrificed after six, twelve, and twenty-four months on the study.

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TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

Synopsis of Treatment Related Changes by Sex and Sacrifice Interval

(IS = interim sacrifice; TS = terminal sacrifice; SDMS = spontaneous death/moribund sacrifice)

Males, 6 month interim sacrifice: There was a treatment related increase of extramedullary hematopoiesis in the spleen of IS (6/10) and SDMS (2/5) males from the RDX 40.0 mg/kg/day group. Lesions of unilateral testicular degeneration were present among 3/10 IS males in the RDX 40.0 mg/kg/day group. This change was accompanied by spermatic granulomas in the epididymis of two of these animals. There was also a significant increase of spermatic granulomas involving the coagulating gland (recorded under prostate) of IS (6/10) and SDMS (2/5) males of the RDX 40.0 mg/kg/day group when compared with the incidence among males of the RDX 0.0 mg/kg/day, RDX 0.3 mg/kg/day, and RDX 1.5 mg/kg/day groups. The no-effect level of RDX in males was 8.0 mg/kg/day.

12 month interim sacrifice: Sinusoidal congestion was present in the spleen of all (10/10) IS males in the RDX 40.0 mg/kg/day group. Lesions of unilateral or bilateral testicular degeneration were present among IS (4/10) and SDMS (4/19) males in the RDX 40.0 mg/kg/day group. Urogenital tract lesions consisting of necrosis of the renal medullary papilla (15/19), luminal distention of the urinary bladder (18/19), and hemorrhagic cystitis (17/19) were confined to SDMS males in the RDX 40.0 mg/kg/day group. There was also diffuse parathyroid hyperplasia in 13/19 of these males. This lesion was accompanied by widespread parenchymal mineralization of visceral organs. These latter changes were regarded as a sequela to the renal injury. The no-effect level of RDX in males was 8.0 mg/kg/day.

24 month terminal sacrifice: A dose related increase of hemosiderin-like pigment was observed in the spleen of TS and SDMS males in the RDX 1.5 mg/kg/day, RDX 8.0 mg/kg/day, and RDX 40.0 mg/kg/day groups. Treatment related inflammatory-obstructive urogenital lesions, similar to those observed at the 12 month sacrifice period in RDX 40.0 mg/kg/day SDMS animals were also present among a large number of SDMS animals of the same dose level from the final study interval. Concurrent renal necrosis, bladder distention and cystitis occurred in one RDX 0.3 mg/kg/day SDMS male. The changes in this male were of comparable severity to those observed among the RDX 40.0 mg/kg/day males from the same study interval. In addition, there were a few SDMS males in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups with lesions of bladder distention and/or cystitis similar to those observed among the RDX 40.0 mg/kg/day group. Secondary lesions of parathyroid hyperplasia with uremic mineralization of visceral organs were observed in RDX 40.0 mg/kg/day SDMS animals with treatment related urogenital lesions. In view of the above observations, a no-effect level of RDX was not determined under the conditions of this study.

Females, 6 month interim sacrifice: There was a treatment related increase of extramedullary hematopoiesis in the spleen of IS females. The incidence in the RDX 40.0 mg/kg/day group was 5/10. The no-effect level of RDX in females was 8.0 mg/kg/day.

Females, 12 month interim sacrifice: A treatment related diffuse sinusoidal congestion was present in the spleen of IS (9/10) and SDMS (1/17) females in the RDX 40.0 mg/kg/day group. The no-effect of RDX in females was 8.0 mg/kg/day.

Females, 24 month terminal sacrifice: There was a treatment related increase in the incidence of lenticular cataracts involving one or both eyes in SDMS females in the RDX 40.0 mg/kg/day group. The no-effect level of RDX in females was 8.0 mg/kg/day.

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Twenty-Four Month Chronic Toxicity/Carcinogenicity Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX) in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Six Month Interim Report
PATHOLOGY REPORT

IIT RESEARCH INSTITUTE

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Six Month Interim Report
Quality Assurance Statement

Necropsy procedures were inspected on May 28, 1981 by Josephine M. Reed. The final draft pathology report was audited January 19 to 21, 1982 by Julie McPhilips and Josephine M. Reed. The study was found to meet Life Sciences Quality Assurance criteria. Specimens and raw data generated during the study will be retained in the IITRI Life Sciences Archives as specified in standard operating procedures.

Josephine M. Reed
Supervisor, Quality Assurance

PATHOLOGICAL SYNOPSIS

Necropsy Observations

No compound-related gross pathologic lesions were observed in Fischer 344 rats from the experimental groups sacrificed after six months on the study, rats that died during this period or those sacrificed *in extremis*.

Microscopic Observations

Treatment-related lesions observed microscopically in six month sacrificed males consisted of the following. There was a treatment-related increase of extramedullary hematopoiesis in the spleen of interim sacrificed (6/10) and spontaneous death and moribund sacrificed (2/5) males from the RDX 40.0 mg/kg/day group. Lesions of unilateral testicular degeneration were present among 3/10 interim sacrificed males in the RDX 40.0 mg/kg/day group. This change was accompanied by spermatic granulomas in the epididymis of two of these animals. There was also a significant increase of spermatic granulomas involving the coagulating gland (recorded under prostate) of interim sacrificed (6/10) and spontaneous deaths and moribund sacrificed (2/5) males of the RDX 40.0 mg/kg/day group when compared with the incidence among males of the RDX 0.0 mg/kg/day, RDX 0.3 mg/kg/day, and RDX 1.5 mg/kg/day groups. The no-effect level of RDX in males was 8.0 mg/kg/day.

In six month interim sacrificed females there was a treatment-related increase of extramedullary hematopoiesis in the spleen of interim sacrificed females. The incidence in the RDX 40.0 mg/kg/day group was 5/10. The no-effect level of RDX in females was 8.0 mg/kg/day.

Statistical Evaluation

Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) lesions of extramedullary hematopoiesis in male and female rats at the 40.0 mg/kg/day dose level, when compared to the control group. Also statistically significant (at $p<0.05$) was the lesion of spermatic granuloma of the prostate in male rats at the 40.0 mg/kg/day dose level.

All other lesions observed microscopically which were submitted for statistical analysis were not significantly different from the control group in male and female rats that either died during this study period, were sacrificed *in extremis*, or were sacrificed after six months on the study.

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Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Six Month Interim Report
NECROPSY OBSERVATIONS

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L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.00	0.30	1.5	8.0	40.0	FEMALES 0.00	0.30	1.5	8.0	40.0
Number of Rats Examined	10	10	10	10	15	11	10	10	10	10
No Gross Lesions	7	8	5	7	4	7	6	6	5	8
SKIN/Subcutis										
Discharge - red					2					
Hair loss					1					
Dark red material/subcutis					1					
Lesion - fighting wounds					1					
Dark red					1					
SKIN AROUND EYE										
Dark red						1				
THYMUS										
Dark red					2					
Firm					2					
Black					1					
Nodules, firm, round, light brown		1								

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
RDX Dose Levels: mg/kg/day										
ESOPHAGUS										
Nodule, firm			1							
LUNG										
Mottled	1		2		1	1	1		1	
Dark red					1					
LIVER										
Nodule/papule								1		
Mass		1				1			1	
Pale									1	
Dark red					2					
Firm					1					
Covered by red material					1					
SPLEEN										
Dark red					1					
Black rimmed					1					
Lighter/pale					1					

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion (RDX Dose Levels: mg/kg/day)	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
SPLEEN (continued)										
Black focus					1					
Dark/black areas					1					
Round edges					1					
KIDNEYS										
Dark red					1					
Covered by red material					1					
URINARY BLADDER										
Tissue, enlongated, mucosa	1									
Distended					1					
Contained red fluid					1					
Wall - red brown					1					
TESTES										
Dark red					1					
Firm					1					

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
EPIDIDYMIS										
Small					1					
SEMINAL VESICLES										
Dark red					1					
UTERUS										
Red							1			
Enlarged/swollen							3			
STOMACH										
Dark red					1					
Distended with gas					1					
DUODENUM										
Dark red					1					
Contained dark green fluidy material					1					

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
JEJUNUM										
Nodule, firm, white, serosal surface	1		1	1	2	2		2	2	1
Contained dark green fluidy material					1					
ILEUM										
Nodule, firm, white, serosal surface	2	1	3	3	1	2	1	3	3	2
Contained yellow material				1						
Contained green fluidy material					1					
CECUM										
Distended with gas					1					
COLON										
Contained clear fluid					1					
RECTUM										
Contained clear fluid					1					

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
EYE										
Red discharge									1	
BRAIN										
Blood clot					1					
RENAL LYMPH NODE										
Enlarged					1					
LIP										
Laceration					1					
NOSE										
Red discharge					1					
TAIL										
Lesion - fighting wounds					1					
Red discharge					1					
Crusted					1					

L06121 SN 6
Six Month Interim Sacrifice
Fischer 344 Rat

GROSS OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.00	MALES 0.30	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.00	FEMALES 0.30	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
MUSCLE AROUND SCIATIC NERVE										
Mass, round, firm, and green					1					
RIGHT SHOULDER										
Lesion - fighting wound					1					

Twenty-Four Month Chronic Toxicity/Carcinogenicity Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX) in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Six Month Interim Report
HISTOPATHOLOGY

IIT RESEARCH INSTITUTE

IITRI Project Number L6121, Study Number 6
Sponsor Project Number DAMD17-79-C-9161

Report of Histopathologic Findings

In accordance with the amended experimental protocol, a histopathologic examination by light microscopy was conducted on hematoxylin-eosin (H&E) stained tissue sections from 100 (50 male and 50 female; 10 each sex per group) Fischer 344 rats of the 6-month Interim Sacrifice of a 24-month chronic toxicity/carcinogenicity study of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). In addition, tissues from one test female (RDX 0 mg/kg/day) and five test males (RDX 40 mg/kg/day) that either died on study or were sacrificed in a moribund condition were also examined. Each group was fed either RDX as a dietary admixture or a control diet until death or sacrifice and then subjected to an extensive necropsy examination. The necropsy of animals, collection and fixation of tissues, and preparation of stained tissue sections were conducted by IIT Research Institute.

The experimental design of the study, as it relates to the histopathologic evaluation, is outlined below:

Treatment Group	Treatment	Number of Males	Number of Females	Dose Level mg/kg/day
I	---	10	11*	0.0
II	RDX	10	10	0.3
III	RDX	10	10	1.5
IV	RDX	10	10	8.0
V	RDX	15*	10	40.0

*includes animals which died on study or were sacrificed moribund

Tissues from animals of the various groups were examined according to Level I (extensive; all animals in the RDX 0 mg/kg/day and RDX 40 mg/kg/day groups) or Level II (partial; all animals in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups) designations as specified in the experimental protocol.

The 'Pathology Report' forms and appendicies which accompany this report constitute an accountability of tissues examined in accordance with the experimental protocol. The grading system and abbreviations used on the 'Pathology Reports' and in the tables are as follows:

Grade 1 = minimal severity	N = within normal limits
Grade 2 = mild severity	L = lesion present
Grade 3 = moderate severity	M = tissue not present
Grade 4 = marked severity	I = tissue section inadequate
P = present	- = tissue not applicable

The incidences of microscopic lesions are summarized by group and sex in the Pathology Appendicies as follows:

Pathology Appendix A: Incidence of Lesions Considered to be Treatment Related

Pathology Appendix B: Incidence Comparison Tables

Pathology Appendix C: Histopathology Incidences Tables

Upon analysis of the data, the following histomorphologic alterations were considered to be treatment-related (summarized in Pathology Appendix A):

Spleen

There was a minimal to mild diffuse increase of extramedullary hematopoiesis within the red pulp of 6 of 10 interim sacrificed males, 2 of 5 died/moribund sacrificed males and 5 of 10 interim sacrificed females of the RDX 40 mg/kg/day group.

Testis/Epididymis

Focal unilateral lesions of germinal cell degeneration, graded as moderate, were observed in 2 of 10 interim sacrificed males of the RDX 40 mg/kg/day group. Diffuse unilateral lesions of marked severity were present in one interim sacrificed male of the same group. This latter lesion was accompanied by an absence of sperm within the ipsilateral epididymal duct. A granulomatous inflammatory response to dead sperm (spermatic granuloma) was also present in a few degenerate tubules of two of the interim sacrificed males with germinal cell degeneration of the testis noted above.

Prostate

There was stasis of nonviable sperm within the lumina of prostate gland acini at the level of the prostatic urethra which was accompanied by infiltrations of epithelioid cell macrophages (spermatic granulomas) in six interim sacrificed and two died/sacrificed moribund males of the RDX 40 mg/kg/day group. These lesions were focal, minimal to mild in severity, and occurred in two of the RDX 40 mg/kg/day interim sacrificed males with lesions of testicular degeneration. After consultation with IITRI staff, it was decided not to examine prostatic tissue from the RDX 8.0 mg/kg/day group at this time. A no-effect level for prostatic granulomas could not, therefore, be established.

Skin

Lesions of chronic dermatitis and associated changes (exudate crusts, acanthosis), involving the tail or other regions of the body, were present among 4 of 10 interim sacrificed and 1 of 5 died/moribund sacrificed males of the RDX 40 mg/kg/day group. These lesions were grossly visible. There were also grossly visible skin lesions described for two additional 40 mg/kg/day males (80-7116, 80-7166) that were not processed for microscopic examination. In the absence of similar gross or histologic findings in the RDX 0 mg/kg/day (control) males, these lesions may be treatment-related, however, the significance of these changes must await the findings at the next sacrifice interval.

With the exception of the above lesions, the remainder of the changes observed among control (RDX 0 mg/kg/day) and RDX receiving animals were ascribed to naturally occurring inflammatory or degenerative processes. The majority of these lesions have been reported as spontaneous in this strain of rat by other investigators (1,2,3). No neoplastic changes were observed in control (RDX 0 mg/kg/day) or RDX receiving animals.

With respect to gross pathologic observations recorded at necropsy, there were a few descriptions of discolored foci on the serosal surface of the jejunum and/or ileum of control (RDX 0 mg/kg/day) and RDX receiving animals. Upon histologic examination of these specimens, submucosal lymphoid nodules (Peyer's Patches) were found and they are regarded as normal structures in this species.

Summary and Conclusions

Treatment related lesions involving both sexes were confined to the spleen, testis, epididymis, and prostate of some interim sacrificed or died/moribund sacrificed rats at the RDX 40 mg/kg/day level. Based on the findings at this sacrifice interval, the maximum no-effect level of RDX appears to be 8 mg/kg/day.

The cause of death among animals that died or were sacrificed in a moribund condition was not established except for one animal (80-7138; RDX 40 mg/kg/day male) that died of respiratory disease.

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REFERENCES:

1. Coleman, G.L. et al, Pathological Changes During Aging in Barrier-Reared Fisher 344 Male Rats, Journal of Gerontology, 32:258-278, 1977.

2. Goodman, D.G. et al, Neoplastic and Non Neoplastic Lesions in Aging F344 Rats, Toxicology and Applied Pharmacology 48:237-248, 1979

3. AFIP Study Set (No. ML005-79) Pathology of the Aging F344 Fisher Rat.

PATHOLOGY APPENDIX A

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
SPLEEN											
Increased extramedullary hematopoieses		0/10	0/10	0/10	0/10	8/15	0/11	0/10	0/10	0/10	5/10
TESTIS											
Germinal cell degeneration, unilateral, focal/multifocal/diffuse		0/10	0/10	0/10	0/10	3/15	-	-	-	-	-
Spermatic granuloma, unilateral, focal		0/10	0/10	0/10	0/10	2/15	-	-	-	-	-
EPIDIDYMIS											
Absence of sperm in ducts, unilateral		0/10	-	-	-	1/15	-	-	-	-	-
PROSTATE											
Spermatic granuloma, focal		0/10	-	-	-	8/15	-	-	-	-	-

PATHOLOGY APPENDIX B
INCIDENCE COMPARISON TABLES

L06121 SM6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

ORGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
BRAIN		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
SPINAL CORD		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
EYE		(10)	-	-	-	(15)	(11)	-	-	-	(10)
OPTIC NERVE		(10)	-	-	-	(14)	(11)	-	-	-	(10)
ADRENAL		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Cortex, increased cytoplasmic vacuolation, unilateral		0/10	-	-	-	0/15	0/11	-	-	-	0/10
Cortex, increased cytoplasmic vacuoloation, bilateral		1/10	-	-	-	0/15	0/11	-	-	-	0/10
SPLEEN		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
Increased extramedullary hematopoiesis		0/10	0/10	0/10	0/10	8/15	0/11	0/10	0/10	0/10	5/10
PANCREAS		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Acinar cell atrophy, focal		0/10	-	-	-	1/15	0/11	-	-	-	0/10

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

ORGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
MESENTERIC LYMPH NODE		(9)	-	-	-	(14)	(11)	-	-	-	(10)
Reticulum cell hyperplasia, focal		0/9	-	-	-	0/14	1/11	-	-	-	0/10
Reactive hyperplasia		0/9	-	-	-	0/14	0/11	-	-	-	0/10
OVARY		-	-	-	-	-	(11)	(10)	(10)	(10)	(10)
UTERUS		-	-	-	-	-	(11)	-	-	-	(10)
Cervicitis, suppurative		-	-	-	-	-	1/11	-	-	-	0/10
TESTIS		(10)	(10)	(10)	(10)	(15)	-	-	-	-	-
Germinal cell degeneration, unilateral, focal/multifocal/diffuse		0/10	0/10	0/10	0/10	3/15	-	-	-	-	-
Spermatic granuloma, unilateral, focal		0/10	0/10	0/10	0/10	2/15	-	-	-	-	-
PROSTATE		(10)	-	-	-	(15)	-	-	-	-	-
Spermatic granuloma, focal		0/10	-	-	-	8/15	-	-	-	-	-
Inflammation, interstitial, subactute		0/10	-	-	-	1/15	-	-	-	-	-

(N) = number of animals for which tissue was represented

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

ORGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
EPIDIDYMIS		(10)	-	-	-	(15)	-	-	-	-	-
Absence of sperm in ducts, unilateral		0/10	-	-	-	1/15	-	-	-	-	-
URINARY BLADDER		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Muscularis, hemorrhage		0/10	-	-	-	1/15	0/11	-	-	-	0/10
Muscularis, inflammation, subacute		0/10	-	-	-	1/15	0/11	-	-	-	0/10
LUNG		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Lymphoid infiltrates, peribronchial/ peribronchiolar, focal		10/10	-	-	-	15/15	11/11	-	-	-	10/10
Bronchopneumonia, suppurative, focal		0/10	-	-	-	1/15	0/11	-	-	-	0/10
Hemorrhage, recent, focal		2/10	-	-	-	1/15	1/11	-	-	-	0/10
Congestion and edema, postmortem		0/10	-	-	-	1/15	0/11	-	-	-	0/10
Congestion, postmortem		0/10	-	-	-	1/15	0/11	-	-	-	0/10
Alveolitis, subacute, focal		0/10	-	-	-	1/15	0/11	-	-	-	0/10
STERNUM		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Marrow, microgranuloma		0/10	-	-	-	0/15	1/11	-	-	-	0/10

- = tissue not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

RGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
HEART		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
Myocarditis, chronic, focal		6/10	5/10	5/10	5/10	1/15	2/11	0/10	0/10	1/10	1/10
Lymphoid infiltrates, interstitial, focal		2/10	1/10	0/10	0/10	0/15	2/11	5/10	2/10	2/10	1/10
Myocardial fibrosis, focal		0/10	0/10	1/10	1/10	1/15	1/11	0/10	1/10	1/10	0/10
LIVER		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
Mononuclear cell infiltrates, portal and sinusoidal, focal		1/10	1/10	0/10	0/10	0/15	0/11	0/10	1/10	1/10	0/10
Mononuclear cell infiltrates, sinusoidal, focal		0/10	0/10	0/10	1/10	0/15	0/11	0/10	1/10	1/10	0/10
Mononuclear cell infiltrates, portal, focal		0/10	0/10	0/10	1/10	0/15	0/11	0/10	0/10	1/10	0/10
Microgranuloma		1/10	0/10	1/10	0/10	0/15	0/11	0/10	0/10	0/10	0/10
Cytoplasmic alteration, vacuolation, focus		0/10	0/10	0/10	0/10	0/15	0/11	0/10	1/10	0/10	0/10
KIDNEY		(10)	(10)	(10)	(10)	(15)	(11)	(10)	(10)	(10)	(10)
Nephropathy, chronic, unilateral		1/10	4/10	1/10	1/10	3/15	3/11	0/10	2/10	1/10	5/10

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

RGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
KIDNEY (con't)											
Nephropathy, chronic, bilateral		7/10	5/10	9/10	9/10	9/15	1/11	0/10	0/10	0/10	0/10
Microconcretions, unilateral, focal		0/10	0/10	1/10	0/10	0/15	2/11	4/10	3/10	2/10	1/10
Microconcretions, bilateral, focal		0/10	0/10	0/10	0/10	1/15	2/11	1/10	4/10	4/10	3/10
ESOPHAGUS		(10)	-	(1)	-	(15)	(11)	-	-	-	(10)
Keratinogenous debris in lumen		0/10	-	1/1	-	0/15	0/11	-	-	-	0/10
DUODENUM		(10)	-	-	-	(14)	(11)	-	-	-	(10)
Microgranuloma, submucosal		0/10	-	-	-	0/14	0/11	-	-	-	0/10
JEJUNUM		(10)	-	-	-	(13)	(11)	-	-	-	(10)
Microgranuloma, submucosal		0/10	-	-	-	0/13	0/11	-	-	-	0/10
Nematode parasite(s) in lumen		1/10	-	-	-	0/13	0/11	-	-	-	0/10
ILEUM		(10)	-	(1)	-	(12)	(11)	-	-	-	(10)
Microgranuloma, submucosal		0/10	-	1/1	-	0/12	0/11	-	-	-	0/10

COL: - = tissue not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

AN sion	Group	MALES	RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES	RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
:CUM			(10)	-	-	-	(12)		(11)	-	-	-	(10)
lematode parasite(s) in lumen			1/10	-	-	-	4/12		1/11	-	-	-	1/10
)LON			(10)	-	-	-	(15)		(11)	-	-	-	(10)
lematode parasite(s) in lumen			1/10	-	-	-	2/15		0/11	-	-	-	2/10
:CTUM			(9)	-	-	-	(15)		(11)	-	-	-	(10)
lematode parasite(s) in lumen			0/9	-	-	-	0/15		0/11	-	-	-	0/10
:IN			(10)	-	-	-	(15)		(11)	-	-	-	(9)
:xudative crusts			0/10	-	-	-	3/15		0/11	-	-	-	0/9
)lcerative dermatitis, focal			0/10	-	-	-	2/15		0/11	-	-	-	0/9
)ermatitis, chronic, focal			0/10	-	-	-	3/15		0/11	-	-	-	0/9
\canthosis, focal			0/10	-	-	-	1/15		0/11	-	-	-	0/9
)ermal necrosis			0/10	-	-	-	1/15		0/11	-	-	-	0/9
\bscess			0/10	-	-	-	1/15		0/11	-	-	-	0/9
\MMARY GLAND			(5)	-	-	-	(11)		(8)	-	-	-	(6)

- tissue not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
Six Month Interim
F344 Rats

INCIDENCE COMPARISON TABLES

ORGAN Lesion	Group	MALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day	FEMALES RDX 0.0 mg/kg/day	RDX 0.3 mg/kg/day	RDX 1.5 mg/kg/day	RDX 8.0 mg/kg/day	RDX 40.0 mg/kg/day
STOMACH		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Glandular, mucosal erosion, focal		1/10	-	-	-	0/15	0/11	-	-	-	0/10
TRACHEA		(10)	-	-	-	(15)	(11)	-	-	-	(10)
Inflammation, chronic, focal		1/10	-	-	-	4/15	2/11	-	-	-	3/10
Inflammation, subacute, focal		0/10	-	-	-	1/15	0/11	-	-	-	0/10
THYROID		(10)	-	-	-	(14)	(11)	-	-	-	(10)
PARATHYROID		(10)	-	-	-	(12)	(11)	-	-	-	(9)
LESIONS (TISSUES NOT SPECIFICALLY REQUIRED BY PROTOCOL FOR ANY GROUP)											
RENAL LYMPH NODE		-	-	-	-	(1)	-	-	-	-	-
Reactive hyperplasia		-	-	-	-	1/1	-	-	-	-	-
Plasmacytosis		-	-	-	-	1/1	-	-	-	-	-
PENILE URETHA		-	-	-	-	(1)	-	-	-	-	-
Mucoid plug in lumen		-	-	-	-	1/1	-	-	-	-	-

CODE: - = tissue not applicable ( ) = number of animals for which tissue was represented

PATHOLOGY APPENDIX C

HISTOPATHOLOGY INCIDENCES TABLE

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN / Lesion	Accession Number 80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574	Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
OPTIC NERVE	N/M	N/N	N/N	N/N	N/N	N/M	N/N	N/N	N/N	N/N	
ADRENAL	N/N	N/N	L/L	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
Cortex, increased cytyplasmic vacuolation, unilateral											
Cortex, increased cytoplasmic vacuolation, bilateral			1								1/10
SPLEEN	N	N	N	N	N	N	N	N	N	N	
Increased extramedullary hematopoiesis											
PANCREAS	N	N	N	N	N	N	N	N	N	N	
Acinar cell atrophy, focal											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574										Incidence
MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	M	N										
Reticulum cell hyperplasia, focal																				
Reactive hyperplasia																				
OVARY	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-										
UTERUS	-	-	-	-	-	-	-	-	-	-										
Cervicitis, suppurative																				
TESTIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
Germinal cell degeneration, unilateral,																				
focal/multifocal/diffuse																				
Germinal cell degeneration, bilateral,																				
focal/multifocal																				
Spermatic granuloma, unilateral, focal																				
Spermatic granuloma, bilateral																				
PROSTATE	N	N	N	N	N	N	N	N	N	N										
Spermatic granuloma, focal																				

Code: 1 = minimal 3 = moderate P = present. N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574										Incidence
PROSTATE (con't)																				
Inflammation, interstitial, subacute																				
EPIDIDYMIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
Absence of sperm in ducts, unilateral																				
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N										
Muscularis, hemorrhage																				
Muscularis, inflammation, subacute																				
LUNG	L	L	L	L	L	L	L	L	L	L										
Lymphoid infiltrates, peribronchial/																				
peribronchiolar, focal	1	2	2	2	2	1	1	2	2	2										10/10
Bronchopneumonia, suppurative, focal																				
Hemorrhage, recent, focal				2	1															2/10
Congestion and edema, postmortem																				
Congestion, postmortem																				
Alveolitis, subacute, focal																				

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574											Incidence
HEART	L	L	L	N	L	N	L	L	L	L											
Myocarditis, chronic, focal	1	1	2				1	1	1												6/10
Lymphoid infiltrates, interstitial, focal					1					1											2/10
Myocardial fibrosis, focal																					
LIVER	N	N	N	L	L	N	N	N	N	N											
Mononuclear cell infiltrates, portal and sinusoidal, focal				1																	1/10
Mononuclear cell infiltrates, sinusoidal, focal																					
Mononuclear cell infiltrates, portal, focal																					
Microgranuloma					1																1/10
Cytoplasmic alteration, vacuolation, focus																					
KIDNEY	N/N	L/L	L/L	L/L	L/L	N/N	N/L	L/L	L/L	L/L											
Nephropathy, chronic, unilateral							1														1/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574											Incidence
KIDNEY (con't)																					
Nephropathy, chronic, bilateral		1	2	1	1			1	1	1											7/10
Microconcretions, unilateral, focal																					
Microconcretions, bilateral, focal																					
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N											
Keratinogeous debris in lumen																					
DUODENUM	N	N	N	N	N	N	N	N	N	N											
Microgranuloma, submucosal																					
JEJUNUM	N	N	N	N	N	N	L	N	N	N											
Microgranuloma, submucosal																					
Nematode parasite(s) in lumen							P														1/10
ILEUM	N	N	N	N	N	N	N	N	N	N											
Microgranuloma, submucosal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574											Incidence
CECUM	N	N	N	N	N	L	N	N	N	N											
Nematode parasite(s) in lumen						P															1/10
COLON	N	N	N	N	N	L	N	N	N	N											
Nematode parasite(s) in lumen						P															1/10
RECTUM	N	N	N	N	N	N	N	N	M	N											
Nematode parasite(s) in lumen																					
SKIN	N	N	N	N	N	N	N	N	N	N											
Exudative crusts																					
Ulcerative dermatitis, focal																					
Dermatitis, chronic, focal																					
Acanthosis, focal																					
Dermal necrosis																					
Abscess																					
MAMMARY GLAND	M	N	N	M	N	N	N	M	M	M											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6509	80-6516	80-6517	80-6525	80-6530	80-6542	80-6557	80-6568	80-6572	80-6574	Incidence
STERNUM	N	N	N	N	N	N	N	N	N	N	
Marrow, microgranuloma											
STOMACH	N	N	N	N	N	N	N	N	N	L	
Glandular, mucosal erosion, focal										1	1/10
TRACHEA	L	N	N	N	N	N	N	N	N	N	
Inflammation, chronic, focal	1										1/10
Inflammation, subacute, focal											
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
PARATHYROID	N/M	N/M	N/N	N/M	N/M	N/M	N/M	N/M	N/N	N/N	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6665	80-6668	80-6669	80-6671	80-6683	80-6684	80-6695	80-6704	80-6725	80-6731											Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N											
SPINAL CORD	N	N	N	N	N	N	N	N	N	N											
LIVER	N	N	N	N	N	N	N	N	L	N											
Mononuclear cell infiltrates, portal																					
and sinusoidal, focal									1												1/10
Mononuclear cell infiltrates,																					
sinusoidal, focal																					
Mononuclear cell infiltrates,																					
portal, focal																					
Microgranuloma																					
Cytoplasmic alteration, vacuolation,																					
focus																					
KIDNEY	N/L	L/L	N/L	N/L	L/L	L/L	L/L	N/L	N/N	L/L											
Nephropathy, chronic, unilateral	1		1	1				1													4/10
Nephropathy, chronic, bilateral		1			1	1	1			1											5/10
Microconcretions, unilateral, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6665	80-6668	80-6669	80-6671	80-6683	80-6684	80-6695	80-6704	80-6725	80-6731											Incidence
KIDNEY (con't)																					
Microconcretions, bilateral, focal																					
HEART	N	L	L	N	L	L	N	N	L	L											
Myocarditis, chronic, focal		1	1		1	1				1											5/10
Lymphoid infiltrates, interstitial, focal									1												1/10
Myocardial fibrosis, focal																					
SPLEEN	N	N	N	N	N	N	N	N	N	N											
Increased extramedullary hematopoiesis																					
OVARY	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-											
TESTIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N											
Germinal cell degeneration, unilateral, focal/multifocal/diffuse																					
Spermatic granuloma, unilateral, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6808	80-6812	80-6814	80-6837	80-6842	80-6843	80-6856	80-6858	80-6873	80-6875	Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	
LIVER	N	N	L	N	N	N	N	N	N	N	
Mononuclear cell infiltrates, portal											
and sinusoidal, focal											
Mononuclear cell infiltrates,											
sinusoidal, focal											
Mononuclear cell infiltrates,											
portal, focal											
Microgranuloma			1								1/10
Cytoplasmic alteration, vacuolation,											
focus											
KIDNEY	L/L	L/L	L/L	L/L	L/L	L/L	L/L	N/L	L/L	L/L	
Nephropathy, chronic, unilateral								1			1/10
Nephropathy, chronic, bilateral	1	1	1	1	1	1	1		1	1	9/10
Microconcretions, unilateral, focal						1					1/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6808	80-6812	80-6814	80-6837	80-6842	80-6843	80-6856	80-6858	80-6873	80-6875	Incidence
KIDNEY (con't)											
Microconcretions, bilateral, focal											
HEART	N	N	L	L	N	L	L	L	L	N	
Myocarditis, chronic, focal			1	1		1	1		1		5/10
Lymphoid infiltrates, interstitial, focal											
Myocardial fibrosis, focal								1			1/10
SPLEEN	N	N	N	N	N	N	N	N	N	N	
Increased extramedullary hematopoiesis											
OVARY	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
TESTIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
Germinal cell degeneration, unilateral, focal/multifocal/diffuse											
Spermatic granuloma, unilateral, focal											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6808	80-6812	80-6814	80-6837	80-6842	80-6843	80-6856	80-6858	80-6873	80-6875											Incidence
LESIONS (TISSUES NOT SPECIFICALLY																					
REQUIRED BY PROTOCOL)																					
ESOPAGUS									L												
Keratogenous debris in lumen									P												1/1
ILEUM										L											
Microgranuloma, submucosal										1											1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits H = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6969	80-6980	80-6983	80-6991	80-6994	80-6999	80-7007	80-7015	80-7016	80-7027											Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N											
SPINAL CORD	N	N	N	N	N	N	N	N	N	N											
LIVER	N	L	N	N	N	N	L	N	N	N											
Mononuclear cell infiltrates, portal																					
and sinusoidal, focal																					
Mononuclear cell infiltrates,																					
sinusoidal, focal		1																			1/10
Mononuclear cell infiltrates,																					
portal, focal							1														1/10
Microgranuloma																					
Cytoplasmic alteration, vacuolation,																					
focus																					
KIDNEY	L/L	L/L	L/L	L/L	N/L	L/L	L/L	L/L	L/L	L/L											
Nephropathy, chronic, unilateral					1																1/10
Nephropathy, chronic, bilateral	1	1	1	1		1	1	1	1	1											9/10
Microconcretions, unilateral, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6969	80-6980	80-6983	80-6991	80-6994	80-6999	80-7007	80-7015	80-7016	80-7027											Incidence
KIDNEY (con't)																					
Microconcretions, bilateral, focal																					
HEART	L	L	N	L	N	L	N	L	L	N											
Myocarditis, chronic, focal	1			1		1		1	1												5/10
Lymphoid infiltrates, interstitial, focal																					
Myocardial fibrosis, focal		1																			1/10
SPLEEN	N	N	N	N	N	N	N	N	N	N											
Increased extramedullary hematopoiesis																					
OVARY	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-											
TESTIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N											
Germinal cell degeneration, unilateral, focal/multifocal/diffuse																					
Spermatic granuloma, unilateral, focal																					

Code: 1 = minimal 2 = mild 3 = moderate 4 = marked P = present N = within normal limits L = lesion present M = tissue not present I = tissue section inadequate - = tissue not applicable

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N						
OPTIC NERVE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	N/N	M/M	N/N	N/M						
ADRENAL	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N						
Cortex, increased cytyplasmic vacuolation, unilateral																					
Cortex, increased cytoplasmic vacuolation, bilateral																					
SPLEEN	N	L	L	N	L	L	N	L	L	N	N	L	L	N	N						
Increased extramedullary hematopoiesis		2	1		2	1		1	1			1	1								8/15
PANCREAS	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N						
Acinar cell atrophy, focal							1														1/15

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	N	N	N	N	N	M	N						
Reticulum cell hyperplasia, focal																					
Reactive hyperplasia																					
OVARY	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-						
UTERUS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-						
Cervicitis, suppurative																					
TESTIS	N/N	N/L	N/N	N/L	N/N	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/N						
Germinal cell degeneration, unilateral, focal/multifocal/diffuse		3		3					4												3/15
Germinal cell degeneration, bilateral, focal/multifocal																					
Spermatic granuloma, unilateral, focal		P							P												2/15
Spermatic granuloma, bilateral																					
PROSTATE	L	L	N	N	N	L	N	L	L	L	N	L	N	L	N						
Spermatic granuloma, focal	2	2				1		1	1	1		1		1							8/15

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
PROSTATE (con't)																					
Inflammation, interstitial, subacute														3							1/15
EPIDIDYMIS	N/N	N/N	N/N	N/M	N/M	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/N						
Absence of sperm in ducts, unilateral									P												1/15
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N						
Muscularis, hemorrhage														3							1/15
Muscularis, inflammation, subacute														1							1/15
LUNG	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L						
Lymphoid infiltrates, peribronchial/																					
peribronchiolar, focal	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2						15/15
Bronchopneumonia, suppurative, focal													3								1/15
Hemorrhage, recent, focal														2							1/15
Congestion and edema, postmortem											3										1/15
Congestion, postmortem												3									1/15
Alveolitis, subacute, focal														1							1/15

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
HEART	N	N	N	L	N	N	N	N	N	N	N	L	N	N	N						
Myocarditis, chronic, focal				1																	1/15
Lymphoid infiltrates, interstitial, focal																					
Myocardial fibrosis, focal												1									1/15
LIVER	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
Mononuclear cell infiltrates, portal and sinusoidal, focal																					
Mononuclear cell infiltrates, sinusoidal, focal																					
Mononuclear cell infiltrates, portal, focal																					
Microgranuloma																					
Cytoplasmic alteration, vacuolation, focus																					
KIDNEY	L/L	L/L	L/L	N/L	L/L	L/L	N/L	N/L	L/L	L/L	N/N	N/N	L/L	L/L	N/N						
Nephropathy, chronic, unilateral				1			1	1													3/15

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
KIDNEY (con't)																					
Nephropathy, chronic, bilateral	1	1	1		1	1			1	1			1	2							9/15
Microconcretions, unilateral, focal																					
Microconcretions, bilateral, focal														2							1/15
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
Keratinogeous debris in lumen																					
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	I						
Microgranuloma, submucosal																					
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	I	N	N	I						
Microgranuloma, submucosal																					
Nematode parasite(s) in lumen																					
ILEUM	N	N	N	N	N	N	N	N	N	N	N	I	I	N	I						
Microgranuloma, submucosal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
CECUM	N	L	N	N	L	L	N	N	L	N	N	I	I	N	I						
Nematode parasite(s) in lumen		P			P	P			P												4/12
COLON	L	N	N	N	N	L	N	N	N	N	N	N	N	N	N						
Nematode parasite(s) in lumen	P					P															2/15
RECTUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
Nematode parasite(s) in lumen																					
SKIN	N	** L	N	** L	** L	N	N	N	L	N	N	N	N	N	L						
Exudative crusts		P		P											P						3/15
Ulcerative dermatitis, focal					3				2												2/15
Dermatitis, chronic, focal		3		3											2						3/15
Acanthosis, focal		1																			1/15
Dermal necrosis		4																			1/15
Abscess		P																			1/15
MAMMARY GLAND	N	M	N	N	N	M	N	N	N	N	M	N	N	M	N						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked. L = lesion present I = tissue section inadequate * = died/sacrificed moribund
** = includes diagnoses made for gross lesions in tail

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
Marrow, microgranuloma																					
STOMACH	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N						
Glandular, mucosal erosion, focal																					
TRACHEA	N	N	N	L	L	N	L	N	N	N	N	N	L	L	N						
Inflammation, chronic, focal				1	1		1						2								4/15
Inflammation, subacute, focal														1							1/15
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	M/M	N/N	N/N						
PARATHYROID	N/N	N/M	N/M	N/N	N/M	N/N	N/N	N/N	N/M	N/M	N/N	M/M	M/M	M/M	N/N						
LESIONS (TISSUES NOT SPECIFICALLY																					
REQUIRED BY PROTOCOL)																					
RENAL LYMPH NODE		L																			
Reactive hyperplasia		2																			1/1
Plasmacytosis		3																			1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7116	80-7119	80-7120	80-7128	80-7132	80-7150	80-7164	80-7166	80-7171	80-7173	80-7110*	80-7112*	80-7138*	80-7143*	80-7149*						Incidence
LESIONS (con't)																					
PENILE URETHA														L							
Mucoid plug in lumen														P							1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*										Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N										
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N										
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
OPTIC NERVE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
ADRENAL	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
Cortex, increased cytyplasmic																					
vacuolation, unilateral																					
Cortex, increased cytoplasmic																					
vacuolation, bilateral																					
SPLEEN	N	N	N	N	N	N	N	N	N	N	N										
Increased extramedullary hematopoiesis																					
PANCREAS	N	N	N	N	N	N	N	N	N	N	N										
Acinar cell atrophy, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
MESENTERIC LYMPH NODE	N	N	N	N	N	L	N	N	N	N	N	
Reticulum cell hyperplasia, focal						2						1/11
Reactive hyperplasia												
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
UTERUS	N	N	N	N	N	N	N	N	L	N	N	
Cervicitis, suppurative									1			1/11
TESTIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
Germinal cell degeneration, unilateral,												
focal/multifocal/diffuse												
Germinal cell degeneration, bilateral,												
focal/multifocal												
Spermatic granuloma, unilateral, focal												
Spermatic granuloma, bilateral												
PROSTATE	-	-	-	-	-	-	-	-	-	-	-	
Spermatic granuloma, focal												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
PROSTATE (con't)												
Inflammation, interstitial, subacute												
EPIDIDYMIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
Absence of sperm in ducts, unilateral												
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	
Muscularis, hemorrhage												
Muscularis, inflammation, subacute												
LUNG	L	L	L	L	L	L	L	L	L	L	L	
Lymphoid infiltrates, peribronchial/												
peribronchiolar, focal	1	2	2	2	2	2	2	2	1	2	2	11/11
Bronchopneumonia, suppurative, focal												
Hemorrhage, recent, focal									2			1/11
Congestion and edema, postmortem												
Congestion, postmortem												
Alveolitis, subacute, focal												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
HEART	N	L	N	L	N	L	N	N	L	L	N	
Myocarditis, chronic, focal									1			2/11
Lymphoid infiltrates, interstitial, focal		1				1						2/11
Myocardial fibrosis, focal										1		1/11
LIVER	N	N	N	N	N	N	N	N	N	N	N	
Mononuclear cell infiltrates, portal and sinusoidal, focal												
Mononuclear cell infiltrates, sinusoidal, focal												
Mononuclear cell infiltrates, portal, focal												
Microgranuloma												
Cytoplasmic alteration, vacuolation, focus												
KIDNEY	N/L	L/L	N/L	L/L	N/L	N/N	N/L	N/N	N/N	N/N	N/L	
Nephropathy, chronic, unilateral			1		1						1	3/11

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
KIDNEY (con't)												
Nephropathy, chronic, bilateral		1										1/11
Microconcretions, unilateral, focal	1						1					2/11
Microconcretions, bilateral, focal		1		1								2/11
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	
Keratinogeous debris in lumen												
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	
Microgranuloma, submucosal												
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	
Microgranuloma, submucosal												
Nematode parasite(s) in lumen												
ILEUM	N	N	N	N	N	N	N	N	N	N	N	
Microgranuloma, submucosal												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
CECUM	N	N	L	N	N	N	N	N	N	N	N	
Nematode parasite(s) in lumen			P									1/11
COLON	N	N	N	N	N	N	N	N	N	N	N	
Nematode parasite(s) in lumen												
RECTUM	N	N	N	N	N	N	N	N	N	N	N	
Nematode parasite(s) in lumen												
SKIN	N	N	N	N	N	N	N	N	N	N	N	
Exudative crusts												
Ulcerative dermatitis, focal												
Dermatitis, chronic, focal												
Acanthosis, focal												
Dermal necrosis												
Abscess												
MAMMARY GLAND	N	N	N	M	M	N	N	N	N	M	N	

Code: 1 = minimal 2 = mild 3 = moderate 4 = marked P = present N = within normal limits L = lesion present M = tissue not present I = tissue section inadequate - = tissue not applicable * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-6587	80-6588	80-6623	80-6627	80-6631	80-6646	80-6647	80-6651	80-6656	80-6618*	Incidence
STERNUM	N	N	N	N	N	N	N	N	N	N	L	
Marrow, microgranuloma											1	
STOMACH	N	N	N	N	N	N	N	N	N	N	N	
Glandular, mucosal erosion, focal												
TRACHEA	L	N	N	L	N	N	N	N	N	N	N	
Inflammation, chronic, focal	1			1								2/11
Inflammation, subacute, focal												
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	N/N	
PARATHYROID	N/M	N/N	N/M	N/N	N/M	N/M	N/M	N/M	N/N	N/M	N/N	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate * = died/sacrificed moribund

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6733	80-6745	80-6750	80-6764	80-6765	80-6768	80-6782	80-6786	80-6798	80-6806											Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N											
SPINAL CORD	N	N	N	N	N	N	N	N	N	N											
LIVER	N	N	N	N	N	N	N	N	N	N											
Mononuclear cell infiltrates, portal																					
and sinusoidal, focal																					
Mononuclear cell infiltrates,																					
sinusoidal, focal																					
Mononuclear cell infiltrates,																					
portal, focal																					
Microgranuloma																					
Cytoplasmic alteration, vacuolation,																					
focus																					
KIDNEY	N/L	N/N	N/L	N/N	N/N	N/N	N/L	L/L	N/N	N/L											
Nephropathy, chronic, unilateral,																					
Nephropathy, chronic, bilateral																					
Microconcretions, unilateral, focal	1		1				1			1											4/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6733	80-6745	80-6750	80-6764	80-6765	80-6768	80-6782	80-6786	80-6798	80-6806	Incidence
KIDNEY (con't)											
Microconcretions, bilateral, focal								1			1/10
HEART	N	L	N	L	L	N	L	N	L	N	
Myocarditis, chronic, focal											
Lymphoid infiltrates, interstitial, focal		1		1	1		1		1		5/10
Myocardial fibrosis, focal											
SPLEEN	N	N	N	N	N	N	N	N	N	N	
Increased extramedullary hematopoiesis											
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
TESTIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
Germinal cell degeneration, unilateral, focal/multifocal/diffuse											
Spermatic granuloma, unilateral, focal											

Code: 1 = minimal, 2 = mild, 3 = moderate, 4 = marked, P = present, N = within normal limits, L = lesion present, M = tissue not present, I = tissue section inadequate, - = tissue not applicable

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6892	80-6898	80-6915	80-6916	80-6919	80-6921	80-6925	80-6948	80-6950	80-6954											Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N											
SPINAL CORD	N	N	N	N	N	N	N	N	N	N											
LIVER	N	N	N	N	L	N	N	N	L	N											
Mononuclear cell infiltrates, portal																					
and sinusoidal, focal									1												1/10
Mononuclear cell infiltrates,																					
sinusoidal, focal					1																1/10
Mononuclear cell infiltrates,																					
portal, focal																					
Microgranuloma																					
Cytoplasmic alteration, vacuolation,																					
focus									2												1/10
KIDNEY	N/L	N/L	L/L	L/L	L/L	N/L	N/L	L/L	N/L	N/N											
Nephropathy, chronic, unilateral,		1					1														2/10
Nephropathy, chronic, bilateral																					
Microconcretions, unilateral, focal	1					1			1												3/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present X = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6892	80-6898	80-6915	80-6916	80-6919	80-6921	80-6925	80-6948	80-6950	80-6954											Incidence
KIDNEY (con't)																					
Microconcretions, bilateral, focal			1	1	1			1													4/10
HEART	N	N	N	N	N	N	L	L	L	N											
Myocarditis, chronic, focal																					
Lymphoid infiltrates, interstitial, focal							1		1												2/10
Myocardial fibrosis, focal								1													1/10
SPLEEN	N	N	N	N	N	N	N	N	N	N											
Increased extramedullary hematopoiesis																					
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N											
TESTIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-											
Germinal cell degeneration, unilateral, focal/multifocal/diffuse																					
Spermatic granuloma, unilateral, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7045	80-7046	80-7048	80-7050	80-7064	80-7072	80-7086	80-7088	80-7100	80-7106	Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	
LIVER	L	N	L	N	N	N	N	N	N	L	
Mononuclear cell infiltrates, portal											
and sinusoidal, focal										1	1/10
Mononuclear cell infiltrates,											
sinusoidal, focal	1										1/10
Mononuclear cell infiltrates,											
portal, focal			1								1/10
Microgranuloma											
Cytoplasmic alteration, vacuolation,											
focus											
KIDNEY	N/N	L/L	L/L	N/N	L/L	N/L	N/N	L/L	N/N	L/L	
Nephropathy, chronic, unilateral,		1									1/10
Nephropathy, chronic, bilateral											
Microconcretions, unilateral, focal		1				1					2/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7045	80-7046	80-7048	80-7050	80-7064	80-7072	80-7086	80-7088	80-7100	80-7106	Incidence
KIDNEY (con't)											
Microconcretions, bilateral, focal			1		1			1		1	4/10
HEART	N	N	N	N	L	N	N	L	L	L	
Myocarditis, chronic, focal										1	1/10
Lymphoid infiltrates, interstitial, focal					1				1		2/10
Myocardial fibrosis, focal								1			1/10
SPLEEN	N	N	N	N	N	N	N	N	N	N	
Increased extramedullary hematopoiesis											
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
TESTIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
Germinal cell degeneration, unilateral, focal/multifocal/diffuse											
Spermatic granuloma, unilateral, focal											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN / Lesion	Accession Number 80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249	Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
OPTIC NERVE	N/N	N/N	N/N	N/M	N/N	N/N	N/M	N/N	N/N	N/N	
ADRENAL	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	
Cortex, increased cytyplasmic vacuolation, unilateral											
Cortex, increased cytoplasmic vacuolation, bilateral											
SPLEEN	N	L	L	L	N	L	N	N	N	L	
Increased extramedullary hematopoiesis		1	1	1		1				1	5/10
PANCREAS	N	N	N	N	N	N	N	N	N	N	
Acinar cell atrophy, focal											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249											Incidence
MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	N	N											
Reticulum cell hyperplasia, focal																					
Reactive hyperplasia																					
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N											
UTERUS	N	N	N	N	N	N	N	N	N	N											
Cervicitis, suppurative																					
TESTIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-											
Germinal cell degeneration, unilateral,																					
focal/multifocal/diffuse																					
Germinal cell degeneration, bilateral,																					
focal/multifocal																					
Spermatic granuloma, unilateral, focal																					
Spermatic granuloma, bilateral																					
PROSTATE	-	-	-	-	-	-	-	-	-	-											
Spermatic granuloma, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249	Incidence
PROSTATE (con't)											
Inflammation, interstitial, subacute											
EPIDIDYMIS	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	
Absence of sperm in ducts, unilateral											
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	
Muscularis, hemorrhage											
Muscularis, inflammation, subacute											
LUNG	L	L	L	L	L	L	L	L	L	L	
Lymphoid infiltrates, peribronchial/											
peribronchiolar, focal	2	2	2	2	2	2	1	2	2	1	10/10
Bronchopneumonia, suppurative, focal											
Hemorrhage, recent, focal											
Congestion and edema, postmortem											
Congestion, postmortem											
Alveolitis, subacute, focal											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249										Incidence
HEART	N	N	N	N	L	L	N	N	N	N										
Myocarditis, chronic, focal					1															1/10
Lymphoid infiltrates, interstitial, focal						1														1/10
Myocardial fibrosis, focal																				
LIVER	N	N	N	N	N	N	N	N	N	N										
Mononuclear cell infiltrates, portal and sinusoidal, focal																				
Mononuclear cell infiltrates, sinusoidal, focal																				
Mononuclear cell infiltrates, portal, focal																				
Microgranuloma																				
Cytoplasmic alteration, vacuolation, focus																				
KIDNEY	N/N	L/L	N/N	L/L	N/N	N/L	L/L	N/N	N/L	N/L										
Nephropathy, chronic, unilateral				1		1	1		1	1										5/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249											Incidence
KIDNEY (con't)																					
Nephropathy, chronic, bilateral																					
Microconcretions, unilateral, focal										1											1/10
Microconcretions, bilateral, focal		1		1			1														3/10
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N											
Keratinogeous debris in lumen																					
DUODENUM	N	N	N	N	N	N	N	N	N	N											
Microgranuloma, submucosal																					
JEJUNUM	N	N	N	N	N	N	N	N	N	N											
Microgranuloma, submucosal																					
Nematode parasite(s) in lumen																					
ILEUM	N	N	N	N	N	N	N	N	N	N											
Microgranuloma, submucosal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249											Incidence
CECUM	L	N	N	N	N	N	N	N	N	N											
Nematode parasite(s) in lumen	P																				1/10
COLON	L	N	N	N	N	N	L	N	N	N											
Nematode parasite(s) in lumen	P						P														2/10
RECTUM	N	N	N	N	N	N	N	N	N	N											
Nematode parasite(s) in lumen																					
SKIN	N	N	N	N	N	M	N	N	N	N											
Exudative crusts																					
Ulcerative dermatitis, focal																					
Dermatitis, chronic, focal																					
Acanthosis, focal																					
Dermal necrosis																					
Abscess																					
MAMMARY GLAND	N	N	M	N	M	M	N	N	M	N											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

L06121 SN6
Six Month Interim
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7186	80-7187	80-7197	80-7213	80-7220	80-7222	80-7230	80-7241	80-7248	80-7249	Incidence
STERNUM	N	N	N	N	N	N	N	N	N	N	
Marrow, microgranuloma											
STOMACH	N	N	N	N	N	N	N	N	N	N	
Glandular, mucosal erosion, focal											
TRACHEA	L	N	N	L	N	N	N	L	N	N	
Inflammation, chronic, focal	1			1				1			3/10
Inflammation, subacute, focal											
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	
PARATHYROID	N/M	N/M	N/N	N/M	N/N	N/N	N/N	N/M	N/M	M/M	

Code: 1 = minimal 3 = moderate P = present N = within normal limits X = tissue not present - = tissue not applicable
2 = mild 4 = marked L = lesion present I = tissue section inadequate

PATHOLOGY APPENDIX D
STATISTICAL EVALUATION OF HISTOPATHOLOGIC LESIONS

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	--	0	--	0	--	0	--	6*	2
	Absent	10	--	10	--	10	--	10	--	4	3
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27
Spleen, sinusoidal congestion											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	10*	0
	Absent	10	--	10	--	10	3	10	--	0	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27

Time = time of sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, increased pigment											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	3	0	1	7*	4	11*	4	0	18*
	Absent	38	14	36	18	18	23	18	22	4	9
Testicular germinal cell degeneration, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	3	0
	Absent	10	--	10	--	10	--	10	--	7	5
12 mos	Present	0	--	0	--	0	1	0	--	4*	4
	Absent	10	--	10	--	10	2	10	--	6	15
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Prostate, spermatic granuloma											
6 mos	Present	0	--	2	--	2	--	1	--	6*	2
	Absent	10	--	8	--	8	--	9	--	4	3
12 mos	Present	0	--	0	--	1	0	1	--	0	0
	Absent	10	--	10	--	9	3	9	--	10	19
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27
Prostate, suppurative inflammation											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	19
24 mos	Present	0	2	1	3	** 2	7**	4*	8	0	19*
	Absent	38	14	35	16	23	20	25	18	4	8

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, medullary papilla necrosis, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	15*
	Absent	10	--	10	--	10	3	10	--	10	4
24 mos	Present	0	0	0	1	0	0	0	0	0	18*
	Absent	38	17	36	18	25	27	29	26	4	9
Kidney, pyelitis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	1	0	0	0	1	** 0	** 5
	Absent	38	17	36	18	25	27	29	25	4	22

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, plyelonephritis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	2	1	1	0	1
	Absent	38	17	36	19	25	25	28	25	4	26
Urinary bladder, luminal distention											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	18*
	Absent	10	--	10	--	10	3	10	--	10	1
24 mos	Present	0	0	0	2	0	1	0	3	1*	24*
	Absent	38	16	36	17	25	26	29	19	3	4

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Urinary bladder, cystitis, hemorrhagic/suppurative/ hemorrhagic - suppurative											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	17*
	Absent	10	--	10	--	10	3	10	--	10	2
24 mos	Present	0	0	0	2	0	1	1	0	0	18*
	Absent	38	16	36	17	25	26	28	22	4	9
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day)									
		0.0		0.3		1.5		8.0		40.0	
		SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS
Lenticular cataracts											
6 mos	Present	0	--	0	--	0	--	0	--	0	--
	Absent	10	--	10	--	10	--	10	--	10	--
12 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	7
24 mos	Present	14	1	4	1	17	3	9	3	23*	9*
	Absent	29	9	41	9	25	9	32	8	5	11
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	0	0	--	0	--	0	--	5*	--
	Absent	10	1	10	--	10	--	10	--	5	--
12 mos	Present	0	0	0	--	0	0	0	--	0	0
	Absent	10	1	10	--	10	1	10	--	10	7
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, sinusoidal congestion											
6 mos	Present	0	0	0	--	0	--	0	--	0	--
	Absent	10	1	10	--	10	--	10	--	10	--
12 mos	Present	0	0	0	--	0	0	0	--	9*	1
	Absent	10	1	10	--	10	1	10	--	1	6
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

Twenty-Four Month Chronic Toxicity/Carcinogenicity Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX) in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twelve Month Interim Report
PATHOLOGY REPORT

IIT RESEARCH INSTITUTE

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twelve Month Interim Report
Quality Assurance Statement

Necropsy procedures were inspected on January 24, 1981 by Josephine M. Reed. The final draft pathology report was audited June 18 to 21, 1982 by Julie McPhilips and Josephine M. Reed. The study was found to meet Life Sciences Quality Assurance criteria. Specimens and raw data generated during the study will be retained in the IITRI Life Sciences Archives as specified in standard operating procedures.

Josephine M. Reed
Supervisor, Quality Assurance

Necropsy Observations

Compound-related gross pathologic lesions were observered in male Fischer 344 rats from the experimental groups sacrificed after twelve months on the study, rats that died during this study period, or those sacrificed *in extremis*. Male rats at the 40.0 mg/kg/day dose level had red-brown fluid in the abdominal cavity, dark brown kidneys with renal pelvis dilatation, distended urinary bladders that contained dark red fluid, small testes, enlarged, red-brown seminal vesicles, enlarged prostate distended with red-brown fluid.

Enlarged dark red spleen observed at necropsy for the 40.0 mg/kg/day dose level in male and female rats was also considered to be compound-related.

Microscopic Observations

Treatment-related lesions observed microscopically in twelve month interim sacrificed males consisted of the following. Sinusoidal congestion was present in the spleen of all (10/10) interim sacrificed males in the RDX 40.0 mg/kg/day group. Lesions of unilateral or bilateral testicular degeneration were present among interim sacrificed (4/10) and spontaneous death and moribund sacrificed (4/19) males in the RDX 40.0 mg/kg/day group. Urogenital tract lesions consisting of necrosis of the renal medullary papilla (15/19), luminal distention of the urinary bladder (18/19), and hemorrhagic cystitis (17/19) were confined to spontaneous death and moribund sacrificed males in the RDX 40.0 mg/kg/day group. There was also diffuse parathyroids hyperplasia in 13/19 of these males. These lesions were accompanied by widespread parenchymal mineralization of visceral organs. These latter changes were regarded as a sequela to the renal injury. The no-effect level of RDX in males was 8.0 mg/kg/day.

In twelve month interim sacrificed females a treatment-related diffuse sinusoidal congestion was present in the spleen of interim sacrificed (9/10) and spontaneous death and moribund sacrificed (1/17) females in the RDX 40.0 mg/kg/day group. The no-effect of RDX in females was 8.0 mg/kg/day.

Statistical Evaluation

Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) lesions of sinusoidal congestion of the spleen at the 40.0 mg/kg/day dose level in male and female rats. Statistically significant (at $p<0.05$) testicular germinal cell degeneration, kidney medullary papillary necrosis, luminal distention of urinary bladder, with hemorrhagic and/or suppurative cystitis at the 40.0 mg/kg/day dose level in male rats were also observed during this study period.

All other lesions observed microscopically that were submitted for statistical analysis were not significantly different from the control group in male and female rats that either died during this study period, were sacrificed *in extremis*, or were sacrificed after twelve months on the study.

Vladislava S. Rac

Vladislava S. Rac, D.V.M., M.S.
Head, Pathology
Pathology Section
Life Sciences Research

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twelve Month Interim Report
NECROPSY OBSERVATIONS

Carol A. Thompson, D.V.M., M.S.
Senior Veterinary Pathologist
Pathology Section
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IIT RESEARCH INSTITUTE

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
Number of Rats Examined	10	10	13	10	29	11	10	11	10	17
No Gross Lesions	4	3	3	2	3	0	4	3	3	4
SKIN/Subcutis										
Yellow, diffuse			1							
Black, focal					2					
Mass					1					
SKIN Around Eye										
Crusted						2	1			
MANDIBULAR SALIVARY GLAND										
Red					1					
HEART										
Firm	1				1					2
Flaccid			1							

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion	RDX Dose Levels: mg/kg/day MALES 0.0	0.3	1.5	8.0	40.0	FEMALES 0.0	0.3	1.5	8.0	40.
THORACIC CAVITY										
Contained fluid, red/brown					2	1				1
THYMUS										
Dark red										1
LUNG										
Mottled red/red	1	1	2	2	3	2	1	1		4
Mottled			2	1	5			1		1
Mass			1							
TRACHEA										
Contained red material				1						
ABDOMINAL CAVITY										
Contained fluid, red/brown					6	1				1
Contained clear fluid					1					

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
LIVER										
Light brown/tan/yellow/pale/gray, focal,										
multifocal	1	1	2		2	1		1	1	1
Red, focal/diffuse					2				1	2
Dark brown focus/diffuse					1	1				
Enlarged/swollen; focal/diffuse	1				1					
Nodule(s)		2				2		1		
Mass(es)		1						1		1
Granular/pitted			1					1		
ADRENAL GLANDS										
Enlarged			2		1					
Dark brown					1					
Tan			1							
SPLEEN										
Dark purple/red/dark	2		1		6	1				5
Black focal/diffuse			1		2					1
Dark brown		1				1				

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40
SPLEEN (continued)										
Firm area		1								
Soft					2					
Enlarged	1		1					1		
KIDNEYS										
Dark brown/brown	2	3	3	3	2	2	3	4	4	4
Tan/gray					6					
Dark red					1					2
Dark foci					1					
Granular/pitted					1					
Mass			1							
Spongy					2					
Dilated pelvis					7					
Pelvis contained red material					1					
URINARY BLADDER										
Distended with fluid, red/brown/yellow		1			20					
Red					4					

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
URINARY BLADDER (continued)										
Adhesions					1					
Abscess					1					
ABDOMINAL FAT										
Mass/nodule/necrosis			1		3		2	1		1
Red area			1		1	1				
DIAPHRAGM										
Rupture		1				2	1		1	
TESTES										
Small			1		9					
Nodule			1							
Mass					1					
Purple, focal					1					
Gray/white					1					
Red					1					
Yellow material subcapsular			1							
Soft					1					

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40
EPIDIDYMIS										
Small			1		1					
Red					1					
SEMINAL VESICLES										
Small			1		2					
Soft					1					
Firm					1					
Contained fluid, red/brown					5					
Black					1					
Red					3					
Yellow					2					
Enlarged					6					
PROSTATE										
Small			1							
Enlarged					8					
Contained fluid, red/dark brown					4					
Yellow					1					

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
PROSTATE (continued)										
Dark brown					1					
Red					2					
Dark areas					1					
OVARIES										
Cyst(s)						1				
Dark red										1
UTERUS										
Enlarged/swollen						1	1	2	1	2
Mass						1				
Dark red										1
Dark gray										2
STOMACH										
Gas filled					2					3
Contained yellow material					1					
Brown focus diffuse - mucosa			1					1		

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
STOMACH (continued)										
Abscess					1					
Adhesions					1					
Nodule			1							
Perforation										
Thickened					1					1
DUODENUM										
Contained material, yellow/red					2					
JEJUNUM										
Contained material, green, yellow/red					2			1		
ILEUM										
Contained material, green, yellow/red					2			1		
Enlarged Peyer's patches	1	2								
CECUM										
Gas filled										3

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L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion	RDX Dose Levels: mg/kg/day MALES 0.0	0.3	1.5	8.0	40.0	FEMALES 0.0	0.3	1.5	8.0	40.0
COLON										
Contained red material					1					
Firm area/nodule					1					
RECUTM										
Rupture					1					
EYES										
Red discharge		1								1
Dark red										1
Small					1					
OPTIC CHIASMA										
Small/thin					1					
Soft					2					
BRAIN										
Dark red area					1					
Soft			1		3					

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40
BRAIN/Meninges										
Red areas	1	1		2	4			1		
VENTRAL SKULL										
Contained red material			1							
CERVICAL VERTEBRAE										
Mass					1					
PITUITARY GLAND										
Mass - dark red	1									
Nodule			1			1				
TAIL										
Fighting wounds					3					
Black foci					1					
Red foci					2					

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L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
NOSE										
Red discharge					1					
HARDEREAN GLAND										
Enlarged			1							
Dark red			1							
PENIS										
Red discharge		1								
Irritated					1					
SCROTAL SAC										
Lacerated					1					
PREPUTIAL GLANDS										
Brown					1					
VULVA										
White discharge										1

L06121 SN 6
Twelve Month Interim Sacrifice
and Deaths 6-12 Months
Fischer 344 Rat

NECROPSY OBSERVATIONS

ORGAN Lesion (RDX Dose Levels: mg/kg/day)	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.
PELVIC LYMPH NODE										
Enlarged					1					
Dark red					1					
URETERS										
Contained fluid					1					
PERIRENAL AREA										
Mass	1		1						1	
PERINEAL REGION										
Rupture					1					
INGUINAL REGION										
Mass		1								1

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twelve Month Interim Report
HISTOPATHOLOGY

IIT RESEARCH INSTITUTE

IITRI Project Number L06121, Study Number 6
Sponsor Project Number DAMD 17-79-C-9161

Report of Histopathologic Findings

Methods

In accordance with the amended experimental protocol, a histopathologic examination by light microscopy was conducted on hematoxylin-eosin (H&E) stained tissue sections from 100 (50 male and 50 female; 10 each sex per group) Fischer 344 rats of the 12-month Interim Sacrifice of a 24-month chronic toxicity/carcinogenicity study of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). In addition, tissues from 31 (22 male and 9 female) rats which either died spontaneously or were sacrificed as moribund during the 6 to 12 month study period were also examined. The distribution of these latter rats by group and sex is indicated in the table below. Each group was fed either RDX as a dietary admixture or a control diet until death or sacrifice and then subjected to an extensive necropsy examination. The necropsy of animals, collection and fixation of tissues, and preparation of stained tissue sections were conducted by IIT Research Institute.

The experimental design of the study, as it relates to the histopathologic evaluation, is outlined below:

Treatment Group	Treatment	Number of Males		Number of Females		Dose Level mg/kg/day
		IS*	SDMS**	IS	SDMS	
I	---	10	-	10	1	0.0
II	RDX	10	-	10	-	0.3
III	RDX	10	3	10	1	1.5
IV	RDX	10	-	10	-	8.0
V	RDX	10	19	10	7	40.0

*interim sacrifice **spontaneous death/moribund sacrifice

Tissues from animals of the various experimental groups were examined according to Level I (extensive; all animals in the RDX 0.0 mg/kg/day and RDX 40.0 mg/kg/day groups) or Level II (partial; all animals in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups) designations as specified in the experimental protocol.

The 'Pathology Report' forms and appendicies which accompany this report constitute an accountability of all tissues examined in accordance with the experimental protocol. The grading system and

abbreviations used on the 'Pathology Reports' and in the tables are as follows:

Grade 1 = minimal severity	N = within normal limits
Grade 2 = mild severity	L = lesion present
Grade 3 = moderate severity	M = tissue not present
Grade 4 = marked severity	I = tissue section inadequate
P = present	- = not applicable

The incidences of microscopic lesions are summarized by group and sex in the Pathology Appendicies as follows:

Pathology Appendix A: Incidence of Lesions Considered to be Treatment Related

Pathology Appendix B: Lesion Incidence Comparison Table

Pathology Appendix C: Histopathology Lesion Severity and Incidence Table

Results

Primary, compound-related, toxicologically significant microscopic lesions confined to the spleen (both sexes) and the urogenital system (males only) wer present in RDX 40.0 mg/kg/day rats which died spontaneously or were sacrificed moribund (SDMS) during study months 6 to 12 or were sacrificed at the 12 month interim (IS). A number of secondary lesions were present in RDX 40.0 mg/kg/day males. In addition, spermatic granulomas of the prostate, thought to be compound-related at the 6 month interim, were present in single males of the RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day groups. The significance of this lesion has been obscured by the findings at this interval. Following is a description of lesions observed.

Spleen (primary lesion)

Diffuse sinusoidal congestion was present in 19 IS (10/10 males; 9/10 females) and 1 SDMS (0/18 males; 1/7 females) animals in the RDX 40.0 mg/kg/day group. With the exception of one IS male graded as moderate, this lesion was mild in severity. A concurrent significant increase in absolute and/or relative spleen weight was not observed.

Testis and Epididymis (primary lesion)

Mild to severe, unilateral or bilateral germinal cell degeneration was present in the testis of IS (4/10) and SDMS (4/19) RDX 40.0 mg/kg/day males. In two IS and three SDMS males this lesion was generally moderate in severity, focal, and unilateral. In the remaining two IS and one SDMS animal, this germinal cell degeneration was more extensive (diffuse) and/or bilateral as well as being accompanied by either an absence or diminution of sperm with cellular debris in the ipsilateral ducts of the epididymis. Bilateral dystrophic mineralization of degenerate seminiferous tubules was present in one IS male which had severe germinal cell degeneration.

Kidney, Ureter, Urinary Bladder (primary lesions)

In SDMS RDX 40.0 mg/kg/day males, unilateral or bilateral necrosis of the renal papilla (15/19) associated with luminal distention of the urinary bladder (18/19) and hemorrhagic cystitis (17/19) was observed. These changes were multifocal to diffuse in extent and minimal to severe in severity. Dilation of the renal pelvis was also noted among these animals, however, since the plane of section was slightly different for each kidney examined, it could not be fully evaluated and was not graded separately. In addition, luminal dilatation of the ureters probably occurred as evidenced by the necropsy observation of 'dilated with fluid' for one SDMS male.

Urogenital System and Peritoneum (secondary lesions)

A large number of secondary lesions involving the urogenital system of SDMS RDX 40.0 mg/kg/day males was also observed. These included uremic mineralization of the renal parenchyma (blood vessels, tubular basement membranes, and tubular epithelial cells) (16/19), uremic mineralization of the urinary bladder wall (4/19), subacute inflammation of the prostate (18/19), subacute inflammation (vesiculitis) of the seminal vesicle (17/19), suppurative pyelitis (1/19), and ascending pyelonephritis with bacterial emboli in renal blood vessels (1/19). Microabscesses were present at some of the sites of prostatitis (2/19) and vesiculitis (2/19). Unilateral or bilateral pericapsular renal lesions of peritonitis were also present (10/19).

The above histomorphologic changes could be closely correlated with the necropsy observations of renal pelvic dilatation, enlargement and/or discoloration of the prostate/seminal vesicles/urinary bladder, and increased amounts of peritoneal fluid of abnormal coloration.

Parathyroid (secondary lesion)

Diffuse parathyroid hyperplasia was present in SDMS RDX 40.0 mg/kg/day males (13/19). Where symmetry could be evaluated (both parathyroids present) this hyperplasia was always bilateral. With a single exception, it was also always mild in severity. This parathyroid hyperplasia was accompanied by renal papillary necrosis and parenchymal mineralization involving the kidney, urinary bladder, lung, heart, and stomach. In view of this association, the parathyroid hyperplasia was regarded as a secondary response associated with uremia rather than a primary (initial) lesion.

Lung (secondary lesion)

Uremic mineralization involving the alveolar septa and or blood vessel walls was present in the lung of SDMS RDX 40.0 mg/kg/day males (8/19). This mineralization was multifocal to diffuse in extent and minimal in severity. Similar mineralization was often present in the heart, stomach, and kidneys of these same animals.

Bacterial emboli were also present in the pulmonary blood vessels of one SDMS RDX 40.0 mg/kg/day male. These were regarded as a sequela to pyelonephritis following urinary tract obstruction.

Heart (secondary lesion)

Uremic mineralization involving blood vessel walls and/or myocardial fibers was present in the heart of most SDMS RDX 40.0 mg/kg/day males (13/19). This mineralization was focal and ranged from minimal to mild severity. Similar mineralization was often present in the lung, stomach,

and kidneys of these same animals.

Stomach (secondary lesion)

Uremic mineralization of blood vessel walls and/or glandular mucosa was present in the stomach of SDMS RDX 40.0 mg/kg/day males (10/18). This mineralization was focal and ranged from minimal to mild in severity. Similar mineralization was often present in the lung, stomach, and kidneys of these same animals.

Prostate (lesion of uncertain significance)

There were single IS males in the RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day groups with spermatic granulomas in the prostate gland. No spermatic granulomas were observed in the prostates of IS or SDMS RDX 40.0 mg/kg/day males. These granulomas resembled those observed at the 6 month interval in the prostates of RDX 40.0 mg/kg/day males. The prostate was not examined for males of the RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day males at the 6 month interval, therefore, a complete determination of a dose-response relationship was precluded at that time.

With the exception of the above described lesions, summarized in Pathology Appendix A, the microscopic changes observed among control (RDX 0.0 mg/kg/day) and RDX receiving animals were ascribed to naturally occurring inflammatory, neoplastic, or degenerative processes. The majority of these lesions have been previously reported as spontaneous in this strain of rat (1,2,3).

At necropsy, one or two animals in each experimental group were described as having 'red matter in the meninges between hemispheres of the brain'. Upon microscopic examination, this 'matter' was identified as normal pineal gland.

Cause of Death Summary

The cause of moribund sacrifice of one RDX 1.5 mg/kg/day male (80-6836) was ascribed to prostatic inflammation. Renal medullary necrosis, uremia, and urinary tract obstruction with secondary inflammation were regarded as the cause of death or moribund sacrifice of 19 RDX 40.0 mg/kg/day males (80-7108, 80-7111, 80-7114, 80-7122, 80-7129, 80-7133, 80-7136, 80-7139, 80-7147, 80-7148, 80-7151, 80-7152, 80-7155, 80-7159, 80-7165, 80-7170, 80-7175, 80-7176, and 80-7181). The cause of death was not established for the one RDX 0.0 mg/kg/day female (80-6528) and six RDX 40.0 mg/kg/day females (80-7195, 80-7196, 80-7218, 80-7237, 80-7247, and 80-7250). Neoplastic disease was responsible for the death or moribund sacrifice of two RDX 1.5 mg/kg/day males (80-6872 and 80-6822), one RDX 1.5 mg/kg/day female (80-6894) and one RDX 40.0 mg/kg/day female (80-7255) These neoplastic lesions consisted of a mixed renal tumor, an adrenal carcinoma, disseminated monocytic leukemia, and a glioma, respectively.

Discussion

The urogenital lesions observed among SDMS RDX 40.0 mg/kg/day males are indicative of urinary stasis due to either partial or complete blockage of the urethra by cellular debris or retention due to painful urination. If urethral obstruction occurred, it probably involved the distal penile segment since obstructive lesions were not evident in the prostatic region. In addition, the pathogenesis of these lesions

was not established. It was not clear whether the renal necrosis occurred first with subsequent urethral blockage and urinary bladder involvement, or whether urinary bladder changes occurred first followed by blockage and retrograde involvement of the kidney, or whether the kidney and urinary bladder were affected simultaneously. Neither was the sequence of involvement of the prostate and seminal vesicle clear. The inflammatory changes in these tissues probably resulted from retrograde involvement following urinary stasis. Likewise, leakage of urine from the distended urinary bladder into the peritoneal cavity was the probable cause of the peritonitis. Regardless of the sequence of events, the renal injury caused a series of subsequent metabolic and morphologic changes involving the parathyroid glands that is consistent with renal or secondary hyperparathyroidism. In this syndrom, the kidney is unable to hydroxylate 25-hydroxycholecalciferol to 1,25-dihydroxycholecalciferol (active form of vitamin D) resulting in lowered calcium absorption in the intestine. This, in turn, results in lowered serum calcium levels which stimulates the parathyroid gland, seen microscopically as hyperplasia, to produce parathormone (PTH) for mobilization of calcium from the bone. In the end stages of renal disease, the kidney is unable to secrete phosphate ion, causing a hyperphosphatemia which leads to further hypocalcemia and parathyroid stimulation since the serum ion concentrations of phosphate and calcium are inversely related. Since the excess calcium resorbed due to PTH secretion cannot remain in the blood, it is deposited in soft tissues throughout the body and is visualized microscopically as uremic mineralization in the heart, stomach, lung, and urinary bladder. The absence of similar changes in the urogenital tract of males examined at the 6 month interval may indicate that a latent period is required before RDX induced changes are manifested.

Microscopic changes, similar to those ascribed to RDX, were also noted in a few RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day males, however since identical lesions occur in low frequency due to naturally occurring diseases, these could not be attributed to the RDX administered to these animals. These changes included prostatitis, vesiculitis, myocardial-renal mineralization, testicular degeneration/necrosis, and absence of sperm in epididymal ducts. In one SDMS RDX 1.5 mg/kg/day male, these changes were regarded as secondary to a mixed renal tumor.

Summary and Conclusions

Compound related lesions in 12 month interim sacrifice animals were confined to the spleen in RDX 40.0 mg/kg/day males and females. Compound related lesions in animals which died spontaneously or were sacrificed as moribund during the 6 to 12 month study interval were confined to males at the RDX 40.0 mg/kg/day level and involved the testis, kidney, urinary bladder, ureter, prostate, seminal vesicle, heart, lung, stomach, and parathyroid.

There were single males at the RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day levels with spermatic granulomas involving the prostate. These were similar to the spermatic granulomas which had been ascribed to RDX treatment at the 6 month interim sacrifice.

Based on the present data, the maximum no-effect level for RDX after 12 months of dietary administration appears to be 8.0 mg/kg/day. If spermatic granulomas of the prostate are considered to be compound related, the maximum no-effect level drops to 0.3 mg/kg/day in males.

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PATHOLOGY APPENDIX A

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

L06121 SN6
TWELVE MONTH INTERIM

FEMALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	SDMS Incidence
SPLEEN	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Congestion, sinusoidal, diffuse	0/10	0/1	0/10	-	0/10	0/1	0/10	-	9/10	1/7

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	SDMS Incidence
SPLEEN	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(18)
Congestion, sinusoidal, diffuse	0/10	-	0/10	-	0/10	0/3	0/10	-	10/10	0/18
TESTIS										
Degeneration, germinal cell, focal/	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
multifocal/diffuse, unilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	3/10	3/19
Degeneration, germinal cell, focal/										
multifocal/diffuse, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/19
Dystrophic mineralization, tubules,										
unilateral/bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	0/19
PROSTATE	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Inflammation, subacute, focal/diffuse	0/10	-	0/10	-	1/10	2/3	2/10	-	0/10	18/19
Microabscess(es)	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	2/19
Spermatic granulomas, focal	0/10	-	0/10	-	1/10	0/3	1/10	-	0/10	0/19
EPIDIDYMIS	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(13)
Absence of sperm, unilateral/										
bilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	2/10	0/18

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was processed

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
EPIDIDYMIS (con't)										
Diminution of sperm, unilateral/										
bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/18
Cellular debris in ducts, unilateral/										
bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/18
SEMINAL VESICLE	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Vesiculitis, subacute, focal/diffuse	1/10	-	0/10	-	0/10	1/3	0/10	-	0/10	17/19
Microabscess(es)	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	2/19
LUNG/MAINSTEM BRONCHI	(10)	-	-	-	-	-	-	-	(10)	(19)
Mineralization, uremic	0/10	-							0/10	8/19
PARATHYROID	(10)	-	-	-	-	-	-	-	(10)	(19)
Hyperplasia, unilateral/bilateral	0/10	-	-	-	-	-	-	-	0/10	13/19
HEART	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Mineralization, vessels, uremic	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	13/19
Mineralization, myocardial, uremic	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	4/19

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
KIDNEY	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Mineralization, uremic, unilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/19
Mineralization, uremic, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	16/19
Necrosis, medullary papilla, unilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	3/19
Necrosis, medullary papilla, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	12/19
Inflammation-peritonitis, pericapsular unilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	3/19
Inflammation-peritonitis, pericapsular bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	7/19
Pyelitis, suppurative, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19
Pyelonephritis, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19
STOMACH	(10)	-	-	-	-	-	-	-	(10)	(18)
Mineralization, uremic, focal	0/10	-	-	-	-	-	-	-	0/10	10/18
URETER	-	-	-	-	-	-	-	-	-	(1)
Dilatation, luminal	-	-	-	-	-	-	-	-	-	1/1

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

MALES F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
URINARY BLADDER	(10)	-	-	-	-	-	-	-	(10)	(19)
Cystitis, hemorrhagic	0/10	-	-	-	-	-	-	-	0/10	17/19
Distention, luminal	0/10	-	-	-	-	-	-	-	0/10	18/19
Mineralization, uremic	0/10	-	-	-	-	-	-	-	0/10	4/19

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) number of animals for which tissue was represented

PATHOLOGY APPENDIX B

LESION INCIDENCE COMPARISON TABLE

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
BRAIN	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
SPINAL CORD (THREE LEVELS)	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
PITUITARY	(10)	-	(10)	-	(9)	(2)	(10)	-	(10)	(18)
Cyst	2/10	-	0/10	-	1/9	0/2	1/10	-	1/10	1/18
Hyperplasia, basophil-cell, focal	2/10	-	1/10	-	5/9	0/2	4/10	-	2/10	0/18
Hyperplasia, chromophobe-cell, focal	0/10	-	0/10	-	1/9	0/2	1/10	-	0/10	0/18
Chromophobe adenoma	1/10	-	0/10	-	0/9	0/2	0/10	-	0/10	0/18
Cytoplasmic vacuolation, basophil-cell	3/10	-	1/10	-	4/10	0/2	3/10	-	2/10	0/18
EYE	(10)	-	-	-	-	-	-	-	(10)	(19)
Phthisis bulbi, unilateral/bilateral	0/10	-	-	-	-	-	-	-	0/10	0/19
OPTIC NERVE	(10)	-	-	-	-	-	-	-	(10)	(15)
ADRENAL	(10)	-	-	-	-	(1)	-	-	(10)	(19)
Cortical adenoma, unilateral/bilateral	0/10	-	-	-	-	0/1	-	-	0/10	1/19

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
ADRENAL (con't)										
Cortex, increased cytoplasmic vacuolation, unilateral/bilateral	2/10	-	-	-	-	0/1	-	-	2/10	1/19
Angiectasis, cortex, unilateral/bilateral	0/10	-	-	-	-	0/1	-	-	0/10	1/19
Carcinoma, cortex, unilateral	0/10	-	-	-	-	1/1	-	-	0/10	0/19
SPLEEN	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(18)
Congestion, sinusoidal, diffuse, agonal	1/10	-	0/10	-	0/10	0/3	0/10	-	0/10	0/18
Congestion, sinusoidal, diffuse	0/10	-	0/10	-	0/10	0/3	0/10	-	10/10	0/18
Increased extramedullary hematopoiesis	0/10	-	0/10	-	0/10	1/3	0/10	-	1/10	0/18
Increased pigment	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/18
PANCREAS	(10)	-	-	-	-	-	-	-	(10)	(18)
Atrophy, acinar cell, focal/multifocal	0/10	-	-	-	-	-	-	-	1/10	0/18
MESENTERIC LYMPH NODE	(9)	-	-	-	-	-	-	-	(10)	(16)
Hyperplasia, reticular cell	3/9	-	-	-	-	-	-	-	3/10	3/16

Code: IS = interim sacrifice; SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
TESTIS	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Interstitial cell tumor, benign, unilateral/bilateral	1/10	-	1/10	-	1/10	0/3	1/10	-	0/10	0/19
Hyperplasia, interstitial cell, focal multifocal, unilateral/bilateral	5/10	-	1/10	-	10/10	1/3	6/10	-	1/10	0/19
Dystrophic mineralization, tubules, unilateral/bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	0/19
Degeneration, germinal cell, focal/ multifocal/diffuse, unilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	3/10	3/19
Degeneration, germinal cell, focal/ multifocal/diffuse, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/19
Mesothelioma, capsule, unilateral/ bilateral	0/10	-	0/10	-	1/10	0/3	0/10	-	0/10	0/19
Necrosis, ischemic, diffuse, unilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/19
PROSTATE	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Inflammation, subacute, focal/diffuse	0/10	-	0/10	-	1/10	2/3	2/10	-	0/10	18/19
Microabscess(es)	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	2/19
Spermatic granulomas, focal	0/10	-	0/10	-	1/10	0/3	1/10	-	0/10	0/19

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	SDMS Incidence
EPIDIDYMIS	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(18)
Absence of sperm, unilateral/										
bilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	2/10	0/18
Diminution of sperm, unilateral/										
bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/18
Cellular debris in ducts, unilateral/										
bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	1/10	1/18
Mesothelioma, capsule, unilateral/										
bilateral	0/10	-	0/10	-	1/10	0/3	0/10	-	0/10	0/18
Spermatic granulomas, unilateral/										
bilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/18
SEMINAL VESICLE	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Vesiculitis, subacute, focal/diffuse	1/10	-	0/10	-	0/10	1/3	0/10	-	0/10	17/19
Microabscess(es)	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	2/19
LUNG/MAINSTEM BRONCHI	(10)	-	-	-	-	-	-	-	(10)	(19)
Lymphoid infiltrates, peribronchial/										
peribronchiolar, focal	10/10	-	-	-	-	-	-	-	10/10	15/19

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)										
Congestion, diffuse, agonal	1/10	-	-	-	-	-	-	-	1/10	1/19
Mineralization, uremic	0/10	-	-	-	-	-	-	-	0/10	8/19
Edema, focal	0/10	-	-	-	-	-	-	-	0/10	1/19
Bacterial emboli, focal/multifocal	0/10	-	-	-	-	-	-	-	0/10	1/19
ESOPHAGUS	(10)	-	-	-	-	-	-	-	(10)	(19)
TRACHEA	(10)	-	-	-	-	-	-	-	(10)	(19)
Inflammation, chronic, focal/diffuse	3/10	-	-	-	-	-	-	-	7/10	7/19
THYROID	(10)	-	-	-	-	-	-	-	(10)	(19)
PARATHYROID	(10)	-	-	-	-	-	-	-	(10)	(19)
Hyperplasia, unilateral/bilateral	0/10	-	-	-	-	-	-	-	0/10	13/19
HEART	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Myocarditis, chronic, focal	8/10	-	6/10	-	8/10	0/3	7/10	-	4/10	1/19
Fibrosis, myocardial, focal	1/10	-	1/10	-	0/10	0/3	0/10	-	1/10	2/19

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
HEART (con't)										
Mineralization, vessels, uremic	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	13/19
Mineralization, myocardial, uremic	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	4/19
Bacterial emboli, focal/multifocal	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19
LIVER	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Bile duct proliferation, focal	6/10	-	6/10	-	6/10	1/3	5/10	-	2/10	0/19
Mononuclear cell infiltrates, sinusoidal, focal	2/10	-	2/10	-	2/10	0/3	3/10	-	2/10	0/19
Mononuclear cell infiltrates, portal, focal	2/10	-	2/10	-	0/10	0/3	2/10	-	0/10	0/19
Necrosis, random, focal	1/10	-	1/10	-	3/10	0/3	2/10	-	0/10	0/19
Cytoplasmic alteration, basophilic, focal	1/10	-	1/10	-	0/10	0/3	0/10	-	0/10	0/19
Cytoplasmic alteration, vacuolation, focal	0/10	-	0/10	-	1/10	0/3	0/10	-	0/10	0/19
Hyperplasia, regenerative, focal	0/10	-	2/10	-	0/10	0/3	0/10	-	0/10	0/19

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
KIDNEY	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Nephropathy, chronic, unilateral/ bilateral	10/10	-	10/10	-	10/10	3/3	10/10	-	9/10	6/19
Inflammation, lymphocytic, unilateral/ bilateral	10/10	-	5/10	-	8/10	2/3	9/10	-	7/10	1/19
Mineralization, uremic, unilateral	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/19
Mineralization, uremic, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	16/19
Cortical cyst, unilateral	1/10	-	0/10	-	0/10	0/3	0/10	-	0/10	0/19
Necrosis, medullary papilla, unilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	3/19
Necrosis, medullary papilla, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	12/19
Inflammation-peritonitis, pericapsular unilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	3/19
Inflammation-peritonitis, pericapsular bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	7/19
Pyelitis, suppurative, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19
Pyelonephritis, bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
KIDNEY (con't)										
Bacterial emboli, focal/multifocal,										
unilateral/bilateral	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	1/19
Mixed tumor, malignant, unilateral,										
with prostatic invasion	0/10	-	0/10	-	0/10	1/3	0/10	-	0/10	0/19
STOMACH	(10)	-	-	-	-	-	-	-	(10)	(18)
Mineralization, uremic, focal	0/10	-	-	-	-	-	-	-	0/10	10/18
DUODENUM	(10)	-	-	-	-	-	-	-	(10)	(17)
JEJUNUM	(10)	-	-	-	-	-	-	-	(10)	(15)
ILEUM	(10)	-	(2)	-	-	-	-	-	(10)	(13)
Hyperplasia, lymphoid, Peyer's Patch	1/10	-	0/2	-	-	-	-	-	0/10	0/13
CECUM	(10)	-	-	-	-	-	-	-	(10)	(14)
Inflammation, acute	0/10	-	-	-	-	-	-	-	0/10	1/14

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TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg.kg.day IS Incidence	RDX 40.0 mg.kg.day SDMS Incidence
CECUM (con't)										
Nematode parasite(s) in lumen	1/10	-	-	-	-	-	-	-	0/10	0/14
COLON	(10)	-	-	-	-	-	-	-	(10)	(15)
Nematode parasite(s) in lumen	3/10	-	-	-	-	-	-	-	2/10	0/15
RECTUM	(10)	-	-	-	-	-	-	-	(10)	(17)
Mucosal inflammation and ulceration, focal	0/10	-	-	-	-	-	-	-	0/10	1/17
SKIN	(10)	-	-	-	-	-	-	-	(10)	(19)
Ulceration, epidermal	0/10	-	-	-	-	-	-	-	0/10	2/19
Exudative crusts	0/10	-	-	-	-	-	-	-	0/10	2/19
Inflammation, dermal	0/10	-	-	-	-	-	-	-	0/10	1/19
Abscess, dermal	0/10	-	-	-	-	-	-	-	0/10	1/19
MAMMARY GLAND	(6)	-	-	-	-	-	-	-	(5)	(9)
Galactoceles	1/6	-	-	-	-	-	-	-	0/5	0/9

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
STERNUM	(10)	-		-		-	-	-	(10)	(18)
BONE MARROW	(10)	-	-	-	-	-	-		(10)	(18)
URINARY BLADDER	(10)	-	-	-	-	-	-	-	(10)	(19)
Cystitis, hemorrhagic	0/10								0/10	17/19
Distention, luminal	0/10								0/10	18/19
Mineralization, uremic	0/10								0/10	4/19
Serosa, microgranuloma	1/10	-	-	-	-	-	-	-	0/10	0/19
LESIONS (TISSUES NOT SPECIFICALLY										
REQUIRED BY PROTOCOL FOR ANY GROUP)										
PINEAL/MENINGES	(1)	-	(1)	-	-	-	(2)	-	(1)	-
Hemorrhage, recent	0/1	-	0/1	-	-	-	0/2	-	1/1	-
SOFT TISSUE	(1)	-	-	-	(1)	(1)	-	-	(2)	(1)
Necrosis/lipogranuloma	1/1	-	-	-	1/1	1/1	-	-	2/2	0/1
Inflammation	0/1	-	-	-	0/1	0/1	-	-	0/2	1/1
PREPUTIAL GLAND	-	-	(1)	-	-	-	-	-	-	-
Adenoma	-	-	1/1	-	-	-	-	-	-	-

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
LESIONS (TISSUES NOT SPECIFICALLY										
REQUIRED BY PROTOCOL FOR ANY										
GROUP) (con't)										
BONE (PARAVERTEBRAL MASS)	-	-	-	-	-	-	-	-	-	(1)
Fibrous osteodystrophy	-	-	-	-	-	-	-	-	-	1/1
Hematoma	-	-	-	-	-	-	-	-	-	1/1
URETER	-	-	-	-	-	-	-	-	-	(1)
Dilatation, luminal	-	-	-	-	-	-	-	-	-	1/1
Inflammation-peritonitis, periserosal	-	-	-	-	-	-	-	-	-	1/1
TAIL	-	-	-	-	-	-	-	-	-	(1)
SKULL	-	-	-	-	-	-	-	-	-	(1)
BLOOD CLOT	-	-	-	-	-	(1)	-	-	-	-
Embolus, adrenal tumor	-	-	-	-	-	1/1	-	-	-	-

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TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
BRAIN	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Glioma, cerebrum	0/10	0/1	0/10	-	0/10	0/1	0/10	-	0/10	1/7
SPINAL CORD (THREE LEVELS)	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
PITUITARY	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Cyst	4/10	0/1	3/10	-	3/10	0/1	3/10	-	5/10	0/7
Hyperplasia, chromophobe-cell, focal	1/10	0/1	2/10	-	1/10	0/1	2/10	-	2/10	0/7
Chromophobe adenoma	1/10	0/1	0/10	-	1/10	0/1	1/10	-	1/10	0/7
EYE	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Harderian gland, dacryoadenitis, focal	0/10	0/1	-	-	-	-	-	-	1/10	0/7
OPTIC NERVE	(10)	(1)	-	-	-	-	-	-	(10)	(6)
ADRENAL	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Angiectasis, cortex, unilateral	0/10	0/1	-	-	-	-	-	-	0/10	1/7
ESOPHAGUS	(10)	(1)	-	-	-	-	-	-	(10)	(7)

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TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
SPLEEN	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Congestion, sinusoidal, diffuse, agonal	0/10	0/1	0/10	-	0/10	0/1	0/10	-	0/10	0/7
Congestion, sinusoidal, diffuse	0/10	0/1	0/10	-	0/10	0/1	0/10	-	9/10	1/7
Monocytic leukemia	0/10	0/1	0/10	-	0/10	1/1	0/10	-	0/10	0/7
PANCREAS	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Atrophy, acinar cell, focal/multifocal	1/10	0/1	-	-	-	-	-	-	0/10	0/7
MESENTERIC LYMPH NODE	(10)	(1)	-	-	-	-	-	-	(10)	(6)
Hyperplasia, reticular cell	2/10	1/1	-	-	-	-	-	-	2/10	2/6
OVARY	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
UTERUS	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Endometrial stromal polyp	1/10	0/1	-	-	-	-	-	-	0/10	0/7
LUNG/MAINSTEM BRONCHI	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Lymphoid infiltrates, peribronchial/ peribronchiolar, focal	10/10	1/1	-	-	-	-	-	-	10/10	7/7

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TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)										
Congestion, diffuse, agonal	0/10	0/1	-	-	-	-	-	-	2/10	0/7
TRACHEA	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Inflammation, chronic, focal/diffuse	0/10	0/1	-	-	-	-	-	-	5/10	4/7
THYROID	(10)	(1)	-	-	-	-	-	-	(10)	(7)
PARATHYROID	(10)	(1)	-	-	-	-	-	-	(10)	(6)
HEART	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Myocarditis, chronic, focal	7/10	1/1	5/10	-	5/10	0/1	3/10	-	6/10	2/7
LIVER	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Bile duct proliferation, focal	3/10	0/1	1/10	-	1/10	0/1	1/10	-	1/10	0/7
Mononuclear cell infiltrates, sinusoidal, focal	3/10	0/1	1/10	-	1/10	0/1	5/10	-	4/10	1/7
Mononuclear cell infiltrates, portal, focal	1/10	0/1	1/10	-	1/10		4/10	-	0/10	0/7

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TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

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LIVER (con't)										
Necrosis, random, focal	0/10	0/1	0/10	-	1/10	0/1	0/10	-	0/10	0/7
Cytoplasmic alteration, basophilic, focal	6/10	1/1	6/10	-	8/10	0/1	8/10	-	4/10	3/7
Cytoplasmic alteration, vacuolation, focal	0/10	0/1	0/10	-	0/10	0/1	0/10	-	1/10	0/7
Hyperplasia, regenerative, focal	0/10	0/1	0/10	-	0/10	0/1	1/10	-	0/10	1/7
Microgranuloma	1/10	1/1	0/10	-	0/10	0/1	1/10	-	0/10	0/7
Microgranulomas, focal	1/10	0/1	0/10	-	1/10	0/1	0/10	-	0/10	0/7
Monocytic leukemia infiltrates	0/10	0/1	0/10	-	0/10	1/1	0/10	-	0/10	0/7
Pigmentation, focal	0/10	0/1	0/10	-	0/10	0/1	1/10	-	0/10	0/7
KIDNEY	(10)	(1)	(10)	-	(10)	(1)	(10)	-	(10)	(7)
Nephropathy, chronic, unilateral/ bilateral	3/10	0/1	6/10	-	8/10	1/1	6/10	-	10/10	4/7
Inflammation, lymphocytic, unilateral/ bilateral	1/10	0/1	2/10	-	1/10	0/1	0/10	-	3/10	0/7
Microconcretions, tubular, unilateral/ bilateral	4/10	1/1	5/10	-	4/10	0/1	4/10	-	5/10	2/7

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
STOMACH	(10)	(1)	-	-	-	-	-	-	(10)	(7)
DUODENUM	(10)	(1)	-	-	-	-	-	-	(10)	(1)
JEJUNUM	(10)	(1)	-	-	-	-	-	-	(10)	(1)
ILEUM	(10)	(1)	-	-	-	-	-	-	(10)	(1)
CECUM	(10)	(1)	-	-	-	-	-	-	(10)	(3)
Nematode parasite(s) in lumen	3/10	0/1	-	-	-	-	-	-	1/10	1/3
COLON	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Nematode parasite(s) in lumen	1/10	0/1	-	-	-	-	-	-	0/10	0/7
RECTUM	(10)	(1)	-	-	-	-	-	-	(10)	(7)
Nematode parasite(s) in lumen	0/10	0/1	-	-	-	-	-	-	1/10	0/7
SKIN	(10)	(1)	-	-	-	-	-	-	(10)	(7)

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 5N6
TWELVE MONTH INTERIM

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day IS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day IS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day IS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day IS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day IS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
MAMMARY GLAND	(9)	(1)	-	-	-	-	-	-	(7)	(5)
STERNUM	(9)	(1)	-	-	-	-	-	-	(10)	(7)
BONE MARROW	(9)	(1)	-	-	-	-	-	-	(10)	(7)
Microgranuloma, focal	5/9	0/1	-	-	-	-	-	-	3/10	0/7
URINARY BLADDER	(10)	(1)	-	-	-	-	-	-	(10)	(7)
LESIONS (TISSUES NOT SPECIFICALLY REQUIRED BY PROTOCOL FOR ANY GROUP)										
SOFT TISSUE, FAT	-	-	(2)	-	(1)	-	(1)	-	(1)	(1)
Necrosis/lipogranuloma	-	-	2/2	-	1/1	-	1/1	-	1/1	1/1
PINEAL/MENINGES	-	-	-	-	(1)	-	-	-	-	-
THYMUS	-	-	-	-	-	-	-	-	-	(1)
TAIL	-	-	-	-	-	-	-	-	-	(1)

Code: IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

PATHOLOGY APPENDIX C

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N		
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N		
PITUITARY	L	N	L	L	N	L	N	L	L	N		
Cyst	P		P								2/10	
Hyperplasia, basophil-cell, focal						1		1			2/10	
Hyperplasia, chromophobe-cell, focal												
Chromophobe adenoma									P		1/10	
Cytoplasmic vacuolation, basophil-cell				1		2		1			3/10	
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
Phthisis bulbi, unilateral/bilateral												
OPTIC NERVE	N/N	N/N	N/M	N/N	N/N	N/N	N/N	N/N	N/N	N/M		
ADRENAL	N/N	N/N	L/L	N/N	N/N	N/N	N/N	N/N	N/L	N/N		
Cortical adenoma, unilateral/bilateral												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
ADRENAL (con't)												
Cortex, increased cytoplasmic												
vacuolation, unilateral/bilateral			2						1		2/10	
Angiectasis, cortex, unilateral/												
bilateral												
SPLEEN	N	N	L	N	N	N	N	N	N	N		
Congestion, sinusoidal, diffuse, agonal			1								1/10	
Congestion, sinusoidal, diffuse												
Increased extramedullary hematopoiesis												
Increased pigment												
PANCREAS	N	N	N	N	N	N	N	N	N	N		
Atrophy, acinar cell, focal/multifocal												
MESENTERIC LYMPH NODE	N	N	N	L	L	N	N	M	N	L		
Hyperplasia, reticular cell				2	1					1	3/9	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
TESTIS	N/N	N/N	N N	L N	N L	L L	L L	L L	N N	L N		
Interstitial cell tumor, benign,												
unilateral/bilateral				P							1/10	
Hyperplasia, interstitial cell, focal/												
multifocal, unilateral/bilateral					2	2	2	2		2	5/10	
Dystrophic mineralization, tubules,												
unilateral/bilateral												
Degeneration, germinal cell, focal/												
multifocal/ diffuse, unilateral												
Degeneration, germinal cell, focal/												
multifocal/diffuse, bilateral												
Mesothelioma, capsule, unilateral/												
bilateral												
Necrosis, ischemic, diffuse, unilateral												
PROSTATE	N	N	N	N	N	N	N	N	N	N		
Inflammation, subacute, focal/diffuse												
Microabscess(es)												
Spermatic granulomas, focal												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
EPIDIDYMIS	N/N	N/N	N N	N/N	N N	N N	N N	N N	N N	N/N		
Absence of sperm, unilateral/												
bilateral												
Diminution of sperm, unilateral/												
bilateral												
Cellular debris in ducts, unilateral/												
bilateral												
Mesothelioma, capsule, unilateral/												
bilateral												
Spermatic granulomas, unilateral/												
bilateral												
SEMINAL VESICLE	N	N	N	N	N	N	N	N	L	N		
Vesiculitis, subacute, focal/diffuse									1		1/10	
Microabscess(es)												
LUNG/MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L		
Lymphoid infiltrates, peribronchial/												
peribronchiolar, focal	2	1	2	2	2	2	2	2	2	2	10/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)												
Congestion, diffuse, agonal									3		1/10	
Mineralization, uremic												
Edema, focal												
Bacterial emboli, focal/multifocal												
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N		
TRACHEA	L	N	N	L	N	N	N	N	L	N		
Inflammation, chronic, focal/diffuse	1			1					1		3/10	
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
PARATHYROID	N/N	N/M	N/N	N/M	N/N	N/M	N/M	N/M	N/M	N/N		
Hyperplasia, unilateral/bilateral												
HEART	L	L	L	L	L	N	L	L	L	L		
Myocarditis, chronic, focal	1	1	1	2	1		1	1		1	8/10	
Fibrosis, myocardial, focal									1		1/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-5555	80-5569	80-6571	IS Incidence	SDMS Incidence
HEART (con't)												
Mineralization, vessels, uremic												
Mineralization, myocardial, uremic												
Bacterial emboli, focal/multifocal												
LIVER	L	N	L	L	L	L	N	L	L	N		
Bile duct proliferation, focal	1		1		1	1		1	1		6/10	
Mononuclear cell infiltrates, sinusoidal, focal	1		1								2/10	
Mononuclear cell infiltrates, portal, focal			1			1					2/10	
Necrosis, random, focal				1							1/10	
Cytoplasmic alteration, basophilic, focal									1		1/10	
Cytoplasmic alteration, vacuolation, focal												
Hyperplasia, regenerative, focal												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
KIDNEY	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L		
Nephropathy, chronic, unilateral/ bilateral	2	2	2	2	2	2	2	2	2	2	10/10	
Inflammation, lymphocytic, unilateral/ bilateral	1	1	1	1	1	1	1	1	1	1	10/10	
Mineralization, uremic, unilateral												
Mineralization, uremic, bilateral												
Cortical cyst, unilateral									P		1/10	
Necrosis, medullary papilla, unilateral												
Necrosis, medullary papilla, bilateral												
Inflammation-peritonitis, pericapsular unilateral												
Inflammation-peritonitis, pericapsular bilateral												
Pyelitis, suppurative, bilateral												
Pyelonephritis, bilateral												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
KIDNEY (con't)												
Bacterial emboli, focal/multifocal,												
unilateral/bilateral												
Mixed tumor, malignant, unilateral,												
with prostatic invasion												
STOMACH	N	N	N	N	N	N	N	N	N	N		
Mineralization, uremic, focal												
DUODENUM	N	N	N	N	N	N	N	N	N	N		
JEJUNUM	N	N	N	N	N	N	N	N	N	N		
ILEUM	N	N	N	N	N	N	N	N	N	L		
Hyperplasia, lymphoid, Peyer's Patch										2	1/10	
CECUM	N	N	N	N	N	N	N	N	L	N		
Inflammation, acute												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
CECUM (con't)												
Nematode parasite(s) in lumen									P		1/10	
COLON	L	N	N	N	N	N	N	L	L	N		
Nematode parasite(s) in lumen	P							P	P		3/10	
RECTUM	N	N	N	N	N	N	N	N	N	N		
Mucosal inflammation and ulceration,												
focal												
SKIN	N	N	N	N	N	N	N	N	N	N		
Ulceration, epidermal												
Exudative crusts												
Inflammation, dermal												
Abscess, dermal												
MAMMARY GLAND	M	M	N	N	N	M	N	N	L	M		
Galactoceles									P		1/6	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6510	80-6526	80-6528	80-6531	80-6537	80-6540	80-6545	80-6555	80-6569	80-6571	IS Incidence	SDMS Incidence
STERNUM	N	N	N	N	N	N	N	N	N	N		
BONE MARROW	N	N	N	N	N	N	N	N	N	N		
URINARY BLADDER	N	N	N	L	N	N	N	N	N	N		
Cystitis, hemorrhagic												
Distention, luminal												
Mineralization, uremic												
Serosa, microgranuloma				P							1/10	
LESIONS (TISSUES NOT SPECIFICALLY												
REQUIRED BY PROTOCOL)												
PINEAL/MENINGES					N							
SOFT TISSUE, FAT									L			
Necrosis/lipogranuloma									P		1/1	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N		
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N		
PITUITARY	N	N	N	N	L	N	N	N	N	N		
Cyst												
Hyperplasia, basophil-cell, focal					1						1/10	
Hyperplasia, chromophobe-cell, focal												
Chromophobe adenoma												
Cytoplasmic vacuolation, basophil-cell					2						1/10	
LIVER	L	L	N	L	L	N	L	L	L	N		
Bile duct proliferation, focal	1	1		1	1		1		2		6/10	
Mononuclear cell infiltrates, sinusoidal, focal							1		1		2/10	
Mononuclear cell infiltrates, portal, focal					1				1		2/10	
Necrosis, random, focal									1		1/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726											IS Incidence	SDMS Incidence
LIVER (con't)																						
Cytoplasmic alteration, basophilic,																						
focal		1																			1/10	
Cytoplasmic alteration, vacuolation,																						
focal																						
Hyperplasia, regenerative, focal								2	1												2/10	
KIDNEY	L/I	N/I	L/I	L/I	L/I	L/I	L/I	L/I	L/I	L/I												
Nephropathy, chronic, unilateral/																						
bilateral	2	1	2	2	2	2	2	2	2	2											10/10	
Inflammation, lymphocytic, unilateral/																						
bilateral	1					1	1	1	1												5/10	
Mineralization, uremic, unilateral																						
Mineralization, uremic, bilateral																						
Cortical cyst, unilateral																						
Necrosis, medullary papilla,																						
unilateral																						
Necrosis, medullary papilla,																						
bilateral																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726											IS Incidence	SDMS Incidence
KIDNEY (con't)																						
Inflammation-peritonitis, pericapsular																						
unilateral																						
Inflammation-peritonitis, pericapsular																						
bilateral																						
Pyelitis, suppurative, bilateral																						
Pyelonephritis, bilateral																						
Bacterial emboli, focal/multifocal,																						
unilateral/bilateral																						
Mixed tumor, malignant, unilateral,																						
with prostatic invasion																						
HEART	L	L	N	L	N	L	L	L	N	L												
Myocarditis, chronic, focal	1	1		1			1	1		1											6/10	
Fibrosis, myocardial, focal						1															1/10	
Mineralization, vessels, uremic																						
Mineralization, myocardial, uremic																						
Bacterial emboli, focal/multifocal																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726										IS Incidence	SDMS Incidence
TESTIS	N/N	N/N	N N	N N	L L	N N	N N	N N	N L	N N											
Interstitial cell tumor, benign, unilateral/bilateral					P															1/10	
Hyperplasia, interstitial cell, focal/multifocal, unilateral/bilateral									1											1/10	
Dystrophic mineralization, tubules, unilateral/bilateral																					
Degeneration, germinal cell, focal/multifocal/ diffuse, unilateral																					
Degeneration, germinal cell, focal/multifocal/diffuse, bilateral																					
Mesothelioma, capsule, unilateral/bilateral																					
Necrosis, ischemic, diffuse, unilateral																					
PROSTATE	N	N	N	N	N	N	N	N	N	N											
Inflammation, subacute, focal/diffuse																					
Microabscess(es)																					
Spermatic granulomas, focal																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726											IS Incidence	SDMS Incidence
EPIDIDYMIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N												
Absence of sperm, unilateral/																						
bilateral																						
Diminution of sperm, unilateral																						
bilateral																						
Cellular debris in ducts, unilateral/																						
bilateral																						
Mesothelioma, capsule, unilateral/																						
bilateral																						
Spermatic granulomas, unilateral/																						
bilateral																						
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N												
Vesiculitis, subacute, focal/diffuse																						
Microabscess(es)																						
SPLEEN	N	N	N	N	N	N	N	N	N	N												
Congestion, sinusoidal, diffuse, agonal																						
Congestion, sinusoidal, diffuse																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726	IS Incidence	SOMS Incidence
SPLEEN (con't)												
Increased extramedullary hematopoiesis												
Increased pigment												
LESIONS (TISSUES NOT SPECIFICALLY												
REQUIRED BY PROTOCOL)												
PREPUTIAL GLAND								L				
Adenoma								P			1/1	
ILEUM	N			N								
MENINGES				N								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SOMS = spontaneous death/moribund sacrifice

LO6121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N		
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N	N	N	N		
PITUITARY	M	L	L	N	L	N	N	L	L	L	N	M	N		
Cyst					P									1/9	0/2
Hyperplasia, basophil-cell, focal		1	1		1				1	1				5/9	0/2
Hyperplasia, chromophobe-cell, focal								1						1/9	0/2
Chromophobe adenoma															
Cytoplasmic vacuolation, basophil-cell		1	2		1					2				4/10	0/2
LIVER	N	N	L	L	L	L	N	N	L	L	L	N	N		
Bile duct proliferation, focal			1	1	1	1			1	1	1			6/10	1/3
Mononuclear cell infiltrates, sinusoidal, focal									1	1				2/10	0/3
Mononuclear cell infiltrates, portal, focal															
Necrosis, random, focal					1				1	1				3/10	0/3

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6610	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**	IS Incidence	SDMS Incidence
LIVER (con't)															
Cytoplasmic alteration, basophilic, focal															
Cytoplasmic alteration, vacuolation, focal						1								1/10	0/3
Hyperplasia, regenerative, focal															
KIDNEY	L	L	L	L	L	L	L	L	L	L	L	L	L		
Nephropathy, chronic, unilateral/ bilateral	2	2	2	2	2	2	2	2	2	2	2	2	1	10/10	3/3
Inflammation, lymphocytic, unilateral/ bilateral		1	1	1	1	1		1	1	1	1		2	8/10	2/3
Mineralization, uremic, unilateral													2	0/10	1/3
Mineralization, uremic, bilateral															
Cortical cyst, unilateral															
Necrosis, medullary papilla, unilateral															
Necrosis, medullary papilla, bilateral															

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**								IS Incidence	SDMS Incidence
KIDNEY (con't)																						
Inflammation-peritonitis, pericapsular																						
unilateral																						
Inflammation-peritonitis, pericapsular																						
bilateral																						
Pyelitis, suppurative, bilateral																						
Pyelonephritis, bilateral																						
Bacterial emboli, focal/multifocal,																						
unilateral/bilateral																						
Mixed tumor, malignant, unilateral,																						
with prostatic invasion													P								0/10	1/3
HEART	L	L	L	L	N	L	L	N	L	L	L	L	L									
Myocarditis, chronic, focal	1	2	1	1		1	1		1	1	1	1									8/10	2/3
Fibrosis, myocardial, focal																						
Mineralization, vessels, uremic													1								0/10	1/3
Mineralization, myocardial, uremic													1								0/10	1/3
Bacterial emboli, focal/multifocal																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**	IS Incidence	SDMS Incidence
TESTIS	N/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	N/L	N/N	L/L		
Interstitial cell tumor, benign, unilateral/bilateral						P								1/10	0/3
Hyperplasia, interstitial cell, focal/multifocal, unilateral/bilateral	1	2	2	1	1	2	2	1	2	2	1			10/10	1/3
Dystrophic mineralization, tubules, unilateral/bilateral															
Degeneration, germinal cell, focal/multifocal/ diffuse, unilateral													3	0/10	1/3
Degeneration, germinal cell, focal/multifocal/diffuse, bilateral															
Mesothelioma, capsule, unilateral/bilateral							P							1/10	0/3
Necrosis, ischemic, diffuse, unilateral													4	0/10	1/3
PROSTATE	N	N	N	N	L	N	N	N	N	L	N	L	L		
Inflammation, subacute, focal/diffuse					1							3	3	1/10	2/3
Microabscess(es)															
Spermatic granulomas, focal										2				1/10	0/3

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6372**	IS Incidence	SDMS Incidence
EPIDIDYMIS	N/N	N/N	N/N	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N	N/N	L/L		
Absence of sperm, unilateral/															
bilateral													P	0/10	1/3
Diminution of sperm, unilateral															
bilateral															
Cellular debris in ducts, unilateral/															
bilateral															
Mesothelioma, capsule, unilateral/															
bilateral							P							1/10	0/3
Spermatic granulomas, unilateral/															
bilateral													3	0/10	1/3
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	L		
Vesiculitis, subacute, focal/diffuse													2	0/10	1/3
Microabscess(es)															
SPLEEN	N	N	N	N	N	N	N	N	N	N	N	L	L		
Congestion, sinusoidal, diffuse, agonal															
Congestion, sinusoidal, diffuse															

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**								IS Incidence	SDMS Incidence
SPLEEN (con't)																						
Increased extramedullary hematopoiesis													4								0/10	1/3
Increased pigment												2									0/10	1/3
LESIONS (TISSUES NOT SPECIFICALLY																						
REQUIRED BY PROTOCOL)																						
SOFT TISSUE, FAT						L					L											
Necrosis/lipogranuloma						P					P										1/1	1/1
ADRENAL											L											
Carcinoma, cortex, unilateral											P											1/1
BLOOD CLOT											L											
Embolus, adrenal tumor											P											1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

LO6121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N		
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N		
PITUITARY	N	N	L	N	L	L	L	L	N	L		
Cyst							P				1/10	
Hyperplasia, basophil-cell, focal			1		1	1				1	4/10	
Hyperplasia, chromophobe-cell, focal										1	1/10	
Chromophobe adenoma												
Cytoplasmic vacuolation, basophil-cell					2	2		2			3/10	
LIVER	N	L	N	L	L	L	N	L	L	L		
Bile duct proliferation, focal				1	1	1		1	1		5/10	
Mononuclear cell infiltrates, sinusoidal, focal				1	1					1	3/10	
Mononuclear cell infiltrates, portal, focal				1						1	2/10	
Necrosis, random, focal		2			1						2/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022	IS Incidence	SDMS Incidence
LIVER (con't)												
Cytoplasmic alteration, basophilic, focal												
Cytoplasmic alteration, vacuolation, focal												
Hyperplasia, regenerative, focal												
KIDNEY	L	L	L	L	L	L	L	L	L	L		
Nephropathy, chronic, unilateral/ bilateral	2	2	2	1	2	2	2	2	2	1	10/10	
Inflammation, lymphocytic, unilateral/ bilateral	1	1	1	1	1	1	1	1	1		9/10	
Mineralization, uremic, unilateral												
Mineralization, uremic, bilateral												
Cortical cyst, unilateral												
Necrosis, medullary papilla, unilateral												
Necrosis, medullary papilla, bilateral												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022											IS Incidence	SDMS Incidence
KIDNEY (con't)																						
Inflammation-peritonitis, pericapsular																						
unilateral																						
Inflammation-peritonitis, pericapsular																						
bilateral																						
Pyelitis, suppurative, bilateral																						
Pyelonephritis, bilateral																						
Bacterial emboli, focal/multifocal,																						
unilateral/bilateral																						
Mixed tumor, malignant, unilateral,																						
with prostatic invasion																						
HEART	L	L	L	L	N	N	L	L	L	N												
Myocarditis, chronic, focal	1	1	1	1			1	1	1												7/10	
Fibrosis, myocardial, focal																						
Mineralization, vessels, uremic																						
Mineralization, myocardial, uremic																						
Bacterial emboli, focal/multifocal																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022	IS Incidence	SDMS Incidence
TESTIS	N/N	N/N	L/L	N/N	L/L	L/L	N/N	L/L	N/L	L/L		
Interstitial cell tumor, benign, unilateral/bilateral										P	1/10	
Hyperplasia, interstitial cell, focal/multifocal, unilateral/bilateral			1		2	2		1	2	1	6/10	
Dystrophic mineralization, tubules, unilateral/bilateral												
Degeneration, germinal cell, focal/multifocal/ diffuse, unilateral												
Degeneration, germinal cell, focal/multifocal/diffuse, bilateral												
Mesothelioma, capsule, unilateral/bilateral												
Necrosis, ischemic, diffuse, unilateral												
PROSTATE	N	N	N	N	N	L	N	L	L	N		
Inflammation, subacute, focal/diffuse								1	1		2/10	
Microabscess(es)												
Spermatic granulomas, focal						2					1/10	

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022										IS Incidence	SDMS Incidence
EPIDIDYMIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N											
Absence of sperm, unilateral/																					
bilateral																					
Diminution of sperm, unilateral																					
bilateral																					
Cellular debris in ducts, unilateral/																					
bilateral																					
Mesothelioma, capsule, unilateral/																					
bilateral																					
Spermatic granulomas, unilateral/																					
bilateral																					
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N											
Vesiculitis, subacute, focal/diffuse																					
Microabscess(es)																					
SPLEEN	N	N	N	N	N	N	N	N	N	N											
Congestion, sinusoidal, diffuse, agonal																					
Congestion, sinusoidal, diffuse																					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022	IS Incidence	SDMS Incidence
SPLEEN (con't)												
Increased extramedullary hematopoiesis												
Increased pigment												
LESIONS (TISSUES NOT SPECIFICALLY												
REQUIRED BY PROTOCOL)												
MENINGES			N		N							

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PITUITARY	L	L	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N
Cyst	P																			
Hyperplasia, basophil-cell, focal		2						2												
Hyperplasia, chromophobe-cell, focal																				
Chromophobe adenoma																				
Cytoplasmic vacuolation, basophil-cell		2						3												
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N
Phthisis bulbi, unilateral/bilateral																P				
OPTIC NERVE	N/M	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	N/M	M/M	N/N	N/N	N/N	N/N	N/M
ADRENAL	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/I
Cortical adenoma, unilateral/bilateral																				P

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

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L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N		
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N		
PITUITARY	N	N	L	N	N	M	N	N	N		
Cyst			P							1/10	1/13
Hyperplasia, basophil-cell, focal										2/10	0/18
Hyperplasia, chromophobe-cell, focal											
Chromophobe adenoma											
Cytoplasmic vacuolation, basophil-cell										2/10	0/18
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
Phthisis bulbi, unilateral/bilateral											
OPTIC NERVE	N/M	N/N	N/N	M/M	N/N	M/M	N/N	N/M	M/M		
ADRENAL	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/N	L/L		
Cortical adenoma, unilateral/bilateral										0/10	1/19

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
ADRENAL (con't)																				
Cortex, increased cytoplasmic vacuolation, unilateral/bilateral				1						1										
Angiectasis, cortex, unilateral/bilateral																				
SPLEEN	L	L	L	L	L	L	L	L	L	L	N	N	N	N	N	N	N	N	N	N
Congestion, sinusoidal, diffuse, agonal																				
Congestion, sinusoidal, diffuse	3	2	2	2	2	2	2	2	2	2										
Increased extramedullary hematopoiesis		1																		
Increased pigment																				
PANCREAS	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N
Atrophy, acinar cell, focal/multifocal								3												
MESENTERIC LYMPH NODE	N	N	N	N	N	N	L	L	N	L	N	N	N	N	N	N	N	L	L	N
Hyperplasia, reticular cell							1	1		1								1	2	

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
ADRENAL (con't)											
Cortex, increased cytoplasmic											
vacuolation, unilateral/bilateral		1								2/10	1/19
Angiectasis, cortex, unilateral/											
bilateral									2	0/10	1/19
SPLEEN	N	N	N	I	N	N	N	N	N		
Congestion, sinusoidal, diffuse, agonal											
Congestion, sinusoidal, diffuse										10/10	0/18
Increased extramedullary hematopoiesis										1/10	0/18
Increased pigment											
PANCREAS	N	N	N	I	N	N	N	N	N		
Atrophy, acinar cell, focal/multifocal										1/10	0/18
MESENTERIC LYMPH NODE	L	N	N	I	N	M	N	N	M		
Hyperplasia, reticular cell	1									3/10	3/16

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L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
TESTIS	N/N	N/L	N/N	N/L	N/N	N/N	N/N	L/L	N/L	N/L	N/L	N/N	N/N	N/N	N/N	N/N	L/L	N/L	N/N	N/N
Interstitial cell tumor, benign, unilateral/bilateral																				
Hyperplasia, interstitial cell, focal/multifocal, unilateral/bilateral		1																		
Dystrophic mineralization, tubules, unilateral/bilateral								P												
Degeneration, germinal cell, focal/multifocal/ diffuse, unilateral				3					3	3	3							2		
Degeneration, germinal cell, focal/multifocal/diffuse, bilateral								4									3			
Mesothelioma, capsule, unilateral/bilateral																				
Necrosis, ischemic, diffuse, unilateral																				
PROSTATE	N	N	N	N	N	N	N	N	N	N	L	L	L	L	L	L	N	L	L	L
Inflammation, subacute, focal/diffuse											2	3	2	2	2	4		2	2	2
Microabscess(es)																				P
Spermatic granulomas, focal																				

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
TESTIS	N/N	N/N	N N	N N	N N	N L	N M	N N	N N		
Interstitial cell tumor, benign, unilateral/bilateral											
Hyperplasia, interstitial cell, focal/multifocal, unilateral/bilateral										1/10	0/19
Dystrophic mineralization, tubules, unilateral/bilateral										1/10	0/19
Degeneration, germinal cell, focal/multifocal/ diffuse, unilateral						3				3/10	3/19
Degeneration, germinal cell, focal/multifocal/diffuse, bilateral										1/10	1/19
Mesothelioma, capsule, unilateral/bilateral											
Necrosis, ischemic, diffuse, unilateral											
PROSTATE	L	L	L	L	L	L	L	L	L		
Inflammation, subacute, focal/diffuse	2	3	3	3	2	2	1	3	2	0/10	18/19
Microabscess(es)		P								0/10	2/19
Spermatic granulomas, focal											

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ORGAN / Lesion — Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
EPIDIDYMIS	N/N	N/N	N N	N/N	N N	N N	N N	L L	N L	N/N	N N	N N	N N	N/N	N/N	N/N	L/L	N/N	N/N	M/M
Absence of sperm, unilateral/																				
bilateral								P	P											
Diminution of sperm, unilateral/																				
bilateral								2									2			
Cellular debris in ducts, unilateral/																				
bilateral									P								P			
Mesothelioma, capsule, unilateral/																				
bilateral																				
Spermatic granulomas, unilateral/																				
bilateral																				
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	L	L	L	L	L	L	N	L	L	L
Vesiculitis, subacute, focal/diffuse											2	2	2	2	2	4		2	1	2
Microabscess(es)																				
LUNG/MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L
Lymphoid infiltrates, peribronchial/																				
peribronchiolar, focal	2	2	2	2	2	2	2	2	2	2	1	2	1	1	1		1			1

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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
EPIDIDYMIS	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
Absence of sperm, unilateral/											
bilateral										2/10	0/18
Diminution of sperm, unilateral/											
bilateral										1/10	1/18
Cellular debris in ducts, unilateral/											
bilateral										1/10	1/18
Mesothelioma, capsule, unilateral/											
bilateral											
Spermatic granulomas, unilateral/											
bilateral											
SEMINAL VESICLE	L	L	L	L	L	L	N	L	L		
Vesiculitis, subacute, focal/diffuse	3	3	2	2	2	2		3	2	0/10	17/19
Microabscess(es)	P	P								0/10	2/19
LUNG/MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	N		
Lymphoid infiltrates, peribronchial/											
peribronchiolar, focal	1	1	1		1	1	2			10/10	15/19

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LUNG/MAINSTEM BRONCHI (con't)																				
Congestion, diffuse, agonal				2								2								
Mineralization, uremic											1		1	1		1			1	
Edema, focal																			3	
Bacterial emboli, focal/multifocal																				
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	L	L	N	L	L	L	N	L	L	N	L	N	L	N	N	N	L	L	N	L
Inflammation, chronic, focal/diffuse	2	1		1	2	1		1	1		1		1				2	1		1
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N
PARATHYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/M	N/N	N/N	N/N	L/L	N/N	N/M	N/N	N/N	L/L	N/N	L/L	L/L	L/L
Hyperplasia, unilateral/bilateral											2					2		2	2	2
HEART	N	N	L	L	N	L	N	L	L	N	L	L	L	L	N	L	N	L	L	L
Myocarditis, chronic, focal			1	1		1			1		1									
Fibrosis, myocardial, focal								1												1

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)											
Congestion, diffuse, agonal										1/10	1/19
Mineralization, uremic						1	1	1		0/10	8/19
Edema, focal										0/10	1/19
Bacterial emboli, focal/multifocal				P						0/10	1/19
ESOPHAGUS	N	N	N	N	N	N	N	N	N		
TRACHEA	L	N	N	N	N	N	L	N	N		
Inflammation, chronic, focal/diffuse	1						1			7/10	7/19
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
PARATHYROID	L/L	L/L	L/L	N/N	L/L	M/L	M/L	L/L	L/L		
Hyperplasia, unilateral/bilateral	2	2	2		2	1	2	2	2	0/10	13/19
HEART	L	N	L	L	N	L	L	L	N		
Myocarditis, chronic, focal										4/10	1/19
Fibrosis, myocardial, focal			1							1/10	2/19

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ORGAN Lesion / Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
HEART (con't)																				
Mineralization, vessels, uremic											2	1	2	2		2		2	2	1
Mineralization, myocardial, uremic																2			1	
Bacterial emboli, focal/multifocal																				
LIVER	N	N	L	N	L	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Bile duct proliferation, focal					1	1														
Mononuclear cell infiltrates, sinusoidal, focal			1			1														
Mononuclear cell infiltrates, portal, focal																				
Necrosis, random, focal																				
Cytoplasmic alteration, basophilic, focal																				
Cytoplasmic alteration, vacuolation, focal																				
Hyperplasia, regenerative, focal																				

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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
HEART (con't)											
Mineralization, vessels, uremic	1		1			2	2	2		0/10	13/19
Mineralization, myocardial, uremic							2	1		0/10	4/19
Bacterial emboli, focal/multifocal				P						0/10	1/19
LIVER	N	N	N	N	N	N	N	N	N		
Bile duct proliferation, focal										2/10	0/19
Mononuclear cell infiltrates, sinusoidal, focal										2/10	0/19
Mononuclear cell infiltrates, portal, focal											
Necrosis, random, focal											
Cytoplasmic alteration, basophilic, focal											
Cytoplasmic alteration, vacuolation, focal											
Hyperplasia, regenerative, focal											

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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
KIDNEY	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L
Nephropathy, chronic, unilateral/ bilateral	1	1		2	1	1	2	1	2	1				2			1		1	
Inflammation, lymphocytic, unilateral/ bilateral	1	1	1	1		1		1	1								1			
Mineralization, uremic, unilateral																				
Mineralization, uremic, bilateral											2	2	2	2		2		2	2	3
Cortical cyst, unilateral																				
Necrosis, medullary papilla, unilateral														2						
Necrosis, medullary papilla, bilateral											3	2	2			3		2	1	2
Inflammation-peritonitis, pericapsular unilateral												P							P	
Inflammation-peritonitis, pericapsular bilateral													P	P	P			P		P
Pyelitis, suppurative, bilateral																2				
Pyelonephritis, bilateral																				

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F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
KIDNEY	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L		
Nephropathy, chronic, unilateral/ bilateral	1	2	1							9/10	6/19
Inflammation, lymphocytic, unilateral/ bilateral										7/10	1/19
Mineralization, uremic, unilateral											
Mineralization, uremic, bilateral	2	1	2		2	2	3	2	1	0/10	16/19
Cortical cyst, unilateral											
Necrosis, medullary papilla, unilateral	2	1								0/10	3/19
Necrosis, medullary papilla, bilateral					3	3	3	2	2	0/10	12/19
Inflammation-peritonitis, pericapsular unilateral					P					0/10	3/19
Inflammation-peritonitis, pericapsular bilateral	P								P	0/10	7/19
Pyelitis, suppurative, bilateral										0/10	1/19
Pyelonephritis, bilateral				3						0/10	1/19

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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
KIDNEY (con't)																				
Bacterial emboli, focal/multifocal,																				
unilateral/bilateral																				
Mixed tumor, malignant, unilateral,																				
with prostatic invasion																				
STOMACH	N	N	N	N	N	N	N	N	N	N	L	L	L	L	I	L	N	L	L	N
Mineralization, uremic, focal											1	2	1	1		1		1	1	
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	I	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	I	N	N	N	I	N	N	N	I	N
Hyperplasia, lymphoid, Peyer's Patch																				
CECUM	N	N	N	N	N	N	N	N	N	N	N	N	I	N	I	N	N	N	N	N
Inflammation, acute																				

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TWELVE MONTH INTERIM
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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151**	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
KIDNEY (con't)											
Bacterial emboli, focal/multifocal,											
unilateral/bilateral				P						0/10	1/19
Mixed tumor, malignant, unilateral,											
with prostatic invasion											
STOMACH	L	L	N	N	N	N	N	L	N		
Mineralization, uremic, focal	1	1						1		0/10	10/18
DUODENUM	N	N	N	I	N	I	N	N	N		
JEJUNUM	N	N	N	I	N	M	N	I	N		
ILEUM	N	N	N	I	N	I	N	I	N		
Hyperplasia, lymphoid, Peyer's Patch											
CECUM	N	L	N	I	N	I	N	I	N		
Inflammation, acute		2								0/10	1/14

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CECUM (con't)																				
Nematode parasite(s) in lumen																				
COLON	N	N	N	N	N	N	N	N	L	L	N	N	N	N	I	N	N	N	N	N
Nematode parasite(s) in lumen									P	P										
RECTUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Mucosal inflammation and ulceration,																				
focal																				
SKIN	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Ulceration, epidermal													2							
Exudative crusts													P							
Inflammation, dermal													3							
Abscess, dermal																				
MAMMARY GLAND	M	M	N	M	N	M	M	N	N	N	N	N	N	M	N	M	M	M	M	N
Galactoceles																				

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CECUM (con't)											
Nematode parasite(s) in lumen											
COLON	N	N	N	I	N	I	N	I	N		
Nematode parasite(s) in lumen										2/10	0/15
RECTUM	N	N	N	L	N	I	N	I	N		
Mucosal inflammation and ulceration, focal				2						0/10	1/17
SKIN	N	N	N	L	N	N	N	L	N		
Ulceration, epidermal								1		0/10	2/19
Exudative crusts								P		0/10	2/19
Inflammation, dermal										0/10	1/19
Abscess, dermal				P						0/10	1/19
MAMMARY GLAND	M	M	N	N	M	N	M	N	M		
Galactoceles											

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STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	L	L	L	L	L	L	L	L	L
Cystitis, hemorrhagic												4	3	3	2	3		4	4	3
Distention, luminal												4	3	4	3	4	3	4	4	3
Mineralization, uremic														1					1	
Serosa, microgranuloma																				
LESIONS (TISSUES NOT SPECIFICALLY																				
REQUIRED BY PROTOCOL)																				
MENINGES	L																			
Hemorrhage, recent	2																			
SOFT TISSUE, FAT		L								L		L								
Necrosis/lipogranuloma		P								P										
Inflammation												3								
BONE (PARAVERTEBRAL MASS)											L									
Fibrous osteodystrophy											3									

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151*	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDHS Incidence
STERNUM	N	N	N	M	N	N	N	N	N		
BONE MARROW	N	N	N	M	N	N	N	N	N		
URINARY BLADDER	L	L	L	L	L	L	L	L	L		
Cystitis, hemorrhagic	1	3	4	3	3	3	3	3	3	0/10	17/19
Distention, luminal	4	4	4	4	4	3	3	3	4	0/10	18/19
Mineralization, uremic	2			2						0/10	4/19
Serosa, microgranuloma											
LESIONS (TISSUES NOT SPECIFICALLY REQUIRED BY PROTOCOL)											
MENINGES											
Hemorrhage, recent										1/1	
SOFT TISSUE, FAT											
Necrosis/lipogranuloma										2/2	
Inflammation											1/1
BONE (PARAVERTEBRAL MASS)											
Fibrous osteodystrophy											1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDHS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7115	80-7121	80-7123	80-7126	80-7135	80-7142	80-7145	80-7168	80-7178	80-7182	80-7108*	80-7111**	80-7114*	80-7122**	80-7129*	80-7133*	80-7136**	80-7139**	80-7147*	80-7148*
BONE (con't)																				
Hematoma											P									
URETER																				
Dilatation, luminal																				
Inflammation-peritonitis, periserosal																				
TAIL																				
SKULL																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SOMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7151*	80-7152*	80-7155*	80-7159*	80-7165**	80-7170*	80-7175**	80-7176*	80-7181*	IS Incidence	SDMS Incidence
BONE (con't)											
Hematoma											1/1
URETER	L										
Dilatation, luminal	3										1/1
Inflammation-peritonitis,periserosal	P										1/1
TAIL		N									
SKULL			N								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-6594	80-6597	80-6598	80-6600	80-6606	80-6621	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N		
Glioma, cerebrum													
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N	N		
PITUITARY	L	L	N	L	L	N	L	N	N	L	N		
Cyst		P		P	P					P		4/10	0/1
Hyperplasia, chromophobe-cell, focal	1											1/10	0/1
Chromophobe adenoma							P					1/10	0/1
EYE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
Harderian gland, dacryoadenitis, focal													
OPTIC NERVE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
ADRENAL	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
Angiectasis, cortex, unilateral													
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N		

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6585	80-6594	80-6597	80-6598	80-6600	80-6606	80-6621	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
SPLEEN	N	N	N	N	N	N	N	N	N	N	N		
Congestion, sinusoidal, diffuse, agonal													
Congestion, sinusoidal, diffuse													
Monocytic leukemia													
PANCREAS	N	N	N	N	N	N	N	L	N	N	N		
Atrophy, acinar cell, focal/multifocal								1				1/10	0/1
MESENTERIC LYMPH NODE	N	L	N	L	N	N	N	N	N	N	L		
Hyperplasia, reticular cell		1		2							1	2/10	1/1
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
UTERUS	N	N	N	N	N	N	N	N	L	N	N		
Endometrial stromal polyp									P			1/10	0/1
LUNG/MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L		
Lymphoid infiltrates, peribronchial/ peribronchiolar, focal	2	1	2	1	2	1	2	2	1	2	2	10/10	1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-6594	80-6597	80-6598	80-6600	80-6606	80-6621	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)													
Congestion, diffuse, agonal													
TRACHEA	N	N	N	N	N	N	N	N	N	N	N		
Inflammation, chronic, focal/diffuse													
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
PARATHYROID	N/N	N/M	N/N	N/N	N/M	N/M	N/M	N/M	N/M	N/N	N/N		
HEART	N	L	L	L	N	N	L	L	L	L	L		
Myocarditis, chronic, focal		1	1	1			1	1	1	1	1	7/10	1/1
LIVER	L	L	N	L	N	N	L	L	L	L	L		
Bile duct proliferation, focal				1				1		1		3/10	0/1
Mononuclear cell infiltrates, sinusoidal, focal		1							1	1		3/10	0/1
Mononuclear cell infiltrates, portal, focal									1			1/10	0/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-5594	80-6597	80-6598	80-6600	80-6606	80-6621	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
LIVER (con't)													
Necrosis, random, focal													
Cytoplasmic alteration, basophilic, focal	1	1		2			1	1	1		1	6/10	1/1
Cytoplasmic alteration, vacuolation, focal													
Hyperplasia, regenerative, focal													
Microgranuloma									1		1	1/10	1/1
Microgranulomas, focal								1				1/10	0/1
Monocytic leukemia infiltrates													
Pigmentation, focal													
KIDNEY	L/L	N/N	N/N	N/N	N/L	L/L	N/N	N/L	N/N	L/L	L/L		
Nephropathy, chronic, unilateral/bilateral	1				1					1		3/10	0/1
Inflammation, lymphocytic, unilateral/bilateral										1		1/10	0/1
Microconcretions, tubular, unilateral/bilateral	1				1	1		1			1	4/10	1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-6594	80-6597	80-6598	80-6600	80-6606	80-6621	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
STOMACH	N	N	N	N	N	N	N	N	N	N	N		
DUODENUM	N	N	N	N	N	N	N	N	N	N	N		
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N		
ILEUM	N	N	N	N	N	N	N	N	N	N	N		
CECUM	L	N	L	N	N	N	N	L	N	N	N		
Nematode parasite(s) in lumen	P		P					P				3/10	0/1
COLON	N	N	N	N	L	N	N	N	N	N	N		
Nematode parasite(s) in lumen					P							1/10	0/1
RECTUM	N	N	N	N	N	N	N	N	N	N	N		
Nematode parasite(s) in lumen													
SKIN	N	N	N	N	N	N	N	N	N	N	N		

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6586	80-6594	80-6597	80-6598	80-6600	80-6606	80-6521	80-6642	80-6648	80-6650	80-6628*	IS Incidence	SDMS Incidence
MAMMARY GLAND	N	N	N	N	N	N	N	N	N	M	N		
STERNUM	N	N	N	N	N	N	N	M	N	N	N		
BONE MARROW	L	N	L	N	N	N	L	M	L	L	N		
Microgranuloma, focal	1		1				2		1	1		5/9	0/1
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N		

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6735	80-6737	80-6755	80-6763	80-6774	80-6781	80-6783	80-6785	80-6789	80-6807	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N		
Glioma, cerebrum												
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N		
PITUITARY	L	N	L	L	L	N	L	N	N	N		
Cyst	P		P				P				3/10	
Hyperplasia, chromophobe-cell, focal				2	2						2/10	
Chromophobe adenoma												
LIVER	L	N	L	L	L	N	N	L	L	N		
Bile duct proliferation, focal			1								1/10	
Mononuclear cell infiltrates, sinusoidal, focal									1		1/10	
Mononuclear cell infiltrates, portal, focal	1										1/10	
Necrosis, random, focal												
Cytoplasmic alteration, basophilic, focal	1		1	1	2			1	1		6/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6735	80-6737	80-6755	80-6763	80-6774	80-6781	80-6783	80-6785	80-6789	80-6807	IS Incidence	SDMS Incidence
LIVER (con't)												
Cytoplasmic alteration, vacuolation, focal												
Hyperplasia, regenerative, focal												
Microgranuloma												
Microgranulomas, focal												
Monocytic leukemia infiltrates												
Pigmentation, focal												
KIDNEY	N/L	L/L	N/N	N/L	L/L	N/N	N/L	L/L	N/N	L/L		
Nephropathy, chronic, unilateral/bilateral	1	1		1	1			1		2	6/10	
Inflammation, lymphocytic, unilateral/bilateral		1								1	2/10	
Microconcretions, tubular, unilateral/bilateral		1			1		1	1		1	5/10	
HEART	N	L	L	N	L	N	N	L	L	N		
Myocarditis, chronic, focal		1	1		1			1	2		5/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6735	80-6737	80-6755	80-6753	80-6774	80-6781	80-6783	80-6785	80-6789	80-6807	IS Incidence	SDHS Incidence
SPLEEN	N	N	N	N	N	N	N	N	N	N		
Congestion, sinusoidal, diffuse, agonal												
Congestion, sinusoidal, diffuse												
Monocytic leukemia												
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
LESIONS (TISSUES NOT SPECIFICALLY												
REQUIRED BY PROTOCOL)												
SOFT TISSUE, FAT		L						L				
Necrosis/lipogranuloma		P						P			2/2	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDHS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6885	80-6897	80-6899	80-6907	80-6918	80-6934	80-6935	80-6939	80-6941	80-6944	80-6894**	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N		
Glioma, cerebrum													
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N	N		
PITUITARY	N	L	L	L	N	L	N	N	L	N	N		
Cyst		P		P		P						3/10	0/1
Hyperplasia, chromophobe-cell, focal			2									1/10	0/1
Chromophobe adenoma									P			1/10	0/1
LIVER	L	N	L	L	L	L	L	L	L	N	L		
Bile duct proliferation, focal							1					1/10	0/1
Mononuclear cell infiltrates, sinusoidal, focal								1				1/10	0/1
Mononuclear cell infiltrates, portal, focal									1			1/10	0/1
Necrosis, random, focal									1			1/10	0/1
Cytoplasmic alteration, basophilic, focal	1		1	1	1	1	1	1	1			8/10	0/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6885	80-6897	80-6899	80-6907	80-6918	80-6934	80-6935	80-6939	80-6941	80-6944	80-6894**	IS Incidence	SDMS Incidence
LIVER (con't)													
Cytoplasmic alteration, vacuolation, focal													
Hyperplasia, regenerative, focal													
Microgranuloma													
Microgranulomas, focal				1								1/10	0/1
Monocytic leukemia infiltrates											P	0/10	1/1
Pigmentation, focal													
KIDNEY	L/L	N/L	L/L	L/L	L/L	N/N	N/L	L/L	N/N	L/L	N/L		
Nephropathy, chronic, unilateral/bilateral	1	1	1	1	1		1	1		1	1	8/10	1/1
Inflammation, lymphocytic, unilateral/bilateral					2							1/10	0/1
Microconcretions, tubular, unilateral/bilateral			1				1	1		1		4/10	0/1
HEART	N	L	L	L	N	N	L	N	L	N	N		
Myocarditis, chronic, focal		1	1	1			1		1			5/10	0/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6885	80-6897	80-6899	80-6907	80-6918	80-6934	80-6935	80-6939	80-6941	80-6944	80-6894**									IS Incidence	SDMS Incidence
SPLEEN	N	N	N	N	N	N	N	N	N	N	L										
Congestion, sinusoidal, diffuse, agonal																					
Congestion, sinusoidal, diffuse																					
Monocytic leukemia											P									0/10	1/1
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N										
LESIONS (TISSUES NOT SPECIFICALLY																					
REQUIRED BY PROTOCOL)																					
SOFT TISSUE, FAT										L											
Necrosis/lipogranuloma										P										1/1	
PINEAL/MENINGES	N																				

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7034	80-7047	80-7051	80-7067	80-7068	80-7080	80-7087	80-7095	80-7101	80-7102	IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N		
Glioma, cerebrum												
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N		
PITUITARY	N	L	N	L	L	N	L	L	N	N		
Cyst					P		P	P			3/10	
Hyperplasia, chromophobe-cell, focal				2			2				2/10	
Chromophobe adenoma		P									1/10	
LIVER	L	L	L	L	L	L	L	L	L	L		
Bile duct proliferation, focal				1							1/10	
Mononuclear cell infiltrates, sinusoidal, focal	1	1			1	1				1	5/10	
Mononuclear cell infiltrates, portal, focal	1			1	1					2	4/10	
Necrosis, random, focal												
Cytoplasmic alteration, basophilic, focal		1	1	1	1	1	1	1		1	8/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7034	80-7047	80-7051	80-7067	80-7068	80-7080	80-7087	80-7095	80-7101	80-7102	IS Incidence	SDMS Incidence
LIVER (con't)												
Cytoplasmic alteration, vacuolation, focal												
Hyperplasia, regenerative, focal				2							1/10	
Microgranuloma									1		1/10	
Microgranulomas, focal												
Monocytic leukemia infiltrates												
Pigmentation, focal				1							1/10	
KIDNEY	L/L	N/L	N/N	L/L	L/L	N/N	N/N	N/L	L/L	L/L		
Nephropathy, chronic, unilateral/bilateral	1			1	1			1	1	1	6/10	
Inflammation, lymphocytic, unilateral/bilateral												
Microconcretions, tubular, unilateral/bilateral	1	1		1	1						4/10	
HEART	L	L	N	N	N	L	N	N	N	N		
Myocarditis, chronic, focal	1	1				1					3/10	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7034	80-7047	80-7051	80-7067	80-7068	80-7080	80-7087	80-7095	80-7101	80-7102	IS Incidence	SDMS Incidence
SPLEEN	N	N	N	N	N	N	N	N	N	N		
Congestion, sinusoidal, diffuse, agonal												
Congestion, sinusoidal, diffuse												
Monocytic leukemia												
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N		
LESIONS (TISSUES NOT SPECIFICALLY												
REQUIRED BY PROTOCOL)												
SOFT TISSUE, FAT			L									
Necrosis/lipogranuloma			P								1/1	

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	L					
Glioma, cerebrum																	P				0/10	1/7
SPINAL CORD (THREE LEVELS)	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
PITUITARY	L	N	N	L	L	N	L	L	L	L	N	N	N	N	N	N	N					
Cyst	P			P	P			P	P												5/10	0/7
Hyperplasia, chromophobe-cell, focal									2	2											2/10	0/7
Chromophobe adenoma							P														1/10	0/7
EYE	N/N	N/L	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	N/N	N/N	N/N	N/N	N/N	N/N					
Harderian gland, dacryoadenitis, focal		1																			1/10	0/7
OPTIC NERVE	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/M	M/M	N/N					
ADRENAL	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/L	N/N	N/N					
Angiectasis, cortex, unilateral															2						0/10	1/7
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
SPLEEN	L	L	L	L	N	L	L	L	L	L	N	N	N	N	N	N	L					
Congestion, sinusoidal, diffuse, agonal																						
Congestion, sinusoidal, diffuse	2	2	2	2		2	2	2	2	2							2				9/10	1/7
Monocytic leukemia																						
PANCREAS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
Atrophy, acinar cell, focal/multifocal																						
MESENTERIC LYMPH NODE	N	N	N	N	N	L	N	L	N	N	N	L	N	N	M	L	N					
Hyperplasia, reticular cell						1		1				1				1					2/10	2/6
OVARY	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N					
UTERUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
Endometrial stromal polyp																						
LUNG/MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L					
Lymphoid infiltrates, peribronchial/																						
peribronchiolar, focal	2	2	2	2	2	2	2	2	2	1	1	1	1	1	2	1	1				10/10	7/7

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
LUNG/MAINSTEM BRONCHI (con't)																						
Congestion, diffuse, agonal					2				2												2/10	0/7
TRACHEA	L	N	N	L	N	N	L	L	N	L	L	N	N	N	L	L	L					
Inflammation, chronic, focal/diffuse	1			1			1	1		1	1				1	1	1				5/10	4/7
THYROID	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N/N	N N	N N	N N	N N	N N	N N	N N					
PARATHYROID	N/M	N/N	N/N	N/N	N/N	N/M	N/M	N/M	N/N	N/N	N N	N M	N N	N M	N N	N N	M M					
HEART	L	L	N	L	L	N	L	N	L	N	N	L	N	L	N	N	N					
Myocarditis, chronic, focal	1	1		1	1		1		1			1		1							6/10	2/7
LIVER	L	L	N	L	L	N	L	N	L	N	L	N	N	L	N	L	L					
Bile duct proliferation, focal				1																	1/10	0/7
Mononuclear cell infiltrates,																						
sinusoidal, focal		1		1	1				1								1				4/10	1/7
Mononuclear cell infiltrates,																						
portal, focal																						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
LIVER (con't)																						
Necrosis, random, focal																						
Cytoplasmic alteration, basophilic, focal	1	1		1			1							1		1	1				4/10	3/7
Cytoplasmic alteration, vacuolation, focal							1														1/10	0/7
Hyperplasia, regenerative, focal											2										0/10	1/7
Microgranuloma																						
Microgranulomas, focal																						
Monocytic leukemia infiltrates																						
Pigmentation, focal																						
KIDNEY	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	L/L	N/L	L/L	N/N	N/L	N/N	L/L	L/L					
Nephropathy, chronic, unilateral/bilateral	1	1	2	1	1	1	1	1	1	1	1			1		1	1				10/10	4/7
Inflammation, lymphocytic, unilateral/bilateral			1				1	1													3/10	0/7
Microconcretions, tubular, unilateral/bilateral	1				1	1		1		1		2				1					5/10	2/7

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
STOMACH	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
DUODENUM	N	N	N	N	N	N	N	N	N	N	I	I	I	I	I	I	N					
JEJUNUM	N	N	N	N	N	N	N	N	N	N	I	I	I	I	I	I	N					
ILEUM	N	N	N	N	N	N	N	N	N	N	I	I	M	I	I	I	N					
CECUM	L	N	N	N	N	N	N	N	N	N	N	I	I	I	L	I	N					
Nematode parasite(s) in lumen	P														P						1/10	1/3
COLON	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
Nematode parasite(s) in lumen																						
RECTUM	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N					
Nematode parasite(s) in lumen									P												1/10	0/7
SKIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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TWELVE MONTH INTERIM
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HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7190	80-7191	80-7201	80-7203	80-7207	80-7221	80-7225	80-7226	80-7232	80-7238	80-7195*	80-7196*	80-7218*	80-7237*	80-7247*	80-7250*	80-7255**				IS Incidence	SDMS Incidence
MAMMARY GLAND	N	N	N	N	M	N	N	M	M	N	N	N	N	M	M	N	N					
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
BONE MARROW	L	L	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N					
Microgranuloma, focal	1	1							1												3/10	0/7
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N					
LESIONS (TISSUES NOT SPECIFICALLY REQUIRED BY PROTOCOL)																						
SOFT TISSUE, FAT	L												L									
Necrosis/lipogranuloma	P												P								1/1	1/1
THYMUS												N										
TAIL											N											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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PATHOLOGY APPENDIX D

STATISTICAL EVALUATION OF HISTOPATHOLOGIC LESIONS

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	--	0	--	0	--	0	--	6*	2
	Absent	10	--	10	--	10	--	10	--	4	3
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27
Spleen, sinusoidal congestion											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	10*	0
	Absent	10	--	10	--	10	3	10	--	0	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27

Time = time of sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, increased pigment											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	3	0	1	7*	4	11*	4	0	18*
	Absent	38	14	36	18	18	23	18	22	4	9
Testicular germinal cell degeneration, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	3	0
	Absent	10	--	10	--	10	--	10	--	7	5
12 mos	Present	0	--	0	--	0	1	0	--	4*	4
	Absent	10	--	10	--	10	2	10	--	6	15
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Prostate, spermatic granuloma											
6 mos	Present	0	--	2	--	2	--	1	--	6*	2
	Absent	10	--	8	--	8	--	9	--	4	3
12 mos	Present	0	--	0	--	1	0	1	--	0	0
	Absent	10	--	10	--	9	3	9	--	10	19
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27
Prostate, suppurative inflammation											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	19
24 mos	Present	0	2	1	3	** 2	7**	4*	8	0	19*
	Absent	38	14	35	16	23	20	25	18	4	8

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, medullary papilla necrosis, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	15*
	Absent	10	--	10	--	10	3	10	--	10	4
24 mos	Present	0	0	0	1	0	0	0	0	0	18*
	Absent	38	17	36	18	25	27	29	26	4	9
Kidney, pyelitis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	1	0	0	0	1	** 0	** 5
	Absent	38	17	36	18	25	27	29	25	4	22

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, plyelonephritis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	2	1	1	0	1
	Absent	38	17	36	19	25	25	28	25	4	26
Urinary bladder, luminal distention											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	18*
	Absent	10	--	10	--	10	3	10	--	10	1
24 mos	Present	0	0	0	2	0	1	0	3	1*	24*
	Absent	38	16	36	17	25	26	29	19	3	4

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Urinary bladder, cystitis, hemorrhagic/suppurative/ hemorrhagic - suppurative											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	17*
	Absent	10	--	10	--	10	3	10	--	10	2
24 mos	Present	0	0	0	2	0	1	1	0	0	18*
	Absent	38	16	36	17	25	26	28	22	4	9
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Lenticular cataracts											
6 mos	Present	0	--	0	--	0	--	0	--	0	--
	Absent	10	--	10	--	10	--	10	--	10	--
12 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	7
24 mos	Present	14	1	4	1	17	3	9	3	23*	9*
	Absent	29	9	41	9	25	9	32	8	5	11
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	0	0	--	0	--	0	--	5*	--
	Absent	10	1	10	--	10	--	10	--	5	--
12 mos	Present	0	0	0	--	0	0	0	--	0	0
	Absent	10	1	10	--	10	1	10	--	10	7
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day)									
		0.0		0.3		1.5		8.0		40.0	
		SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS
Spleen, sinusoidal congestion											
6 mos	Present	0	0	0	--	0	--	0	--	0	--
	Absent	10	1	10	--	10	--	10	--	10	--
12 mos	Present	0	0	0	--	0	0	0	--	9*	1
	Absent	10	1	10	--	10	1	10	--	1	6
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

Twenty-Four Month Chronic Toxicity/Carcinogenicity Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX) in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twenty-Four Month Interim Report
PATHOLOGY REPORT

IIT RESEARCH INSTITUTE

Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twenty-Four Month Interim Report
Quality Assurance Statement

Necropsy procedures were inspected on November 29, 1982 by Josephine M. Reed. The final draft pathology report was audited between October 17 and November 2, 1983 by Julie McPhilips and Josephine M. Reed. The study was found to meet Life Sciences Quality Assurance criteria. Specimens and raw data generated during the study will be retained in the IITRI Life Sciences Archives as specified in standard operating procedures.

Josephine M. Reed
Supervisor, Quality Assurance

PATHOLOGICAL SYNOPSIS

Necropsy Observations

Compound-related gross pathologic lesions were observed in Fischer 344 rats from the experimental groups sacrificed at twenty-four months on the study, rats that died during this period or those sacrificed *in extremis*.

Male rats at the 40.0 mg/kg/day dose level had dark-brown, enlarged kidneys; enlarged, dark-red seminal vesicles; enlarged, dark-red prostate and distended urinary bladder. Compound-related lesions observed at necropsy in female rats at the 40.0 mg/kg/day dose level were white, opaque and small eyes.

Microscopic Observations

Treatment-related lesions observed microscopically at twenty-four month terminal sacrifice follow. A dose-related increase of hemosiderin-life pigment was observed in the spleen of terminal sacrificed and spontaneous death and moribund sacrificed males in the RDX 1.5 mg/kg/day, RDX 8.0 mg/kg/day, and RDX 40.0 mg/kg/day groups. Treatment-related inflammatory-obstructive urogenital lesions, similar to those observed at the twelve month sacrifice period in RDX 40.0 mg/kg/day spontaneous death and moribund sacrifice animals were also present among a large number of spontaneous death and moribund sacrificed animals of the same dose level from the final study interval. Concurrent renal necrosis, bladder distention and cystitis occurred in one RDX 0.3 mg/kg/day spontaneous death and moribund sacrificed male. The changes in this male were of comparable severity to those observed among the RDX 40.0 mg/kg/day males from the same study interval. In addition, there were a few spontaneous death and moribund sacrificed males in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups with lesions of bladder distention and/or cystitis similar to those observed among the RDX 40.0 mg/kg/day group. Secondary lesions of parathyroid hyperplasia with uremic mineralization of visceral organs were observed in RDX 40.0 mg/kg/day spontaneous death and moribund sacrificed animals with treatment-related urogenital lesions. In view of the above observations, a no-effect level of RDX was not determined under the conditions of this study.

In twenty-four month terminal sacrificed females there was a treatment-related increase in the incidence of lenticular cataracts involving one or both eyes in spontaneous death and moribund sacrificed females in the RDX 40.0 mg/kg/day group. The no-effect level of RDX in females was 8.0 mg/kg/day.

Statistical Analysis

Statistical evaluation of histopathologic lesions revealed statistically significant (at $p<0.05$) increased pigment in the spleen and suppurative inflammation of the prostate at the 1.5 mg/kg/day, 8.0 mg/kg/day and 40.0 mg/kg/day dose levels in male rats. Kidneys, medullary papillary necrosis, pyelitis, urinary bladder lumenal distention, cystitis in male rats at the 40.0 mg/kg/day dose level were statistically significant (at $p<0.05$) when

compared to the control group.

In female rats at the 40.0 mg/kg/day dose level lenticular cataracts were statistically significant (at $p<0.05$).

All other lesions observed microscopically which were submitted for statistical analysis were not significantly different from the control group in male and female rats that either died during this study perior, were sacrificed *in extremis*, or were sacrificed after twenty-four months on the study.

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Twenty-Four Month Chronic Toxicity/Carcinogenicity
Study of HEXAHYDRO-1,3,5,-TRINITRO-1,3,5,-TRIAZINE (RDX)
in the Fischer 344 Rat

IITRI Project No. L6121
Study Number 6

Twenty-Four Month Interim Report
NECROPSY OBSERVATIONS

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IIT RESEARCH INSTITUTE

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Moribund Sacrifices and
Spontaneous Deaths

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
Number of Rats Examined	17	19	27	26	17	10	10	12	14	20
No Gross Lesions	0	0	0	0	0	0	0	0	0	0
SKIN/Subcutis										
Edema	1			1		1			1	
Yellow discoloration - generalized	6	5	6	4			2	1	4	2
Mass(es)		6	7	10	1	2	1	3	1	4
Nodule(s)		1						1		
Thickened/enlarged						1		1		1
Crusted/red crusted					2					
Covered with red material							1			
SKIN - Around the Eyes										
Crusted red material/red discharge	3		2	1		4		1	2	4
Black material		1	3						1	2
MANDIBULAR SALIVARY GLAND										
Mass		1		1		1				1
Enlarged		2		1					1	1

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MANDIBULAR SALIVARY GLAND (continued)										
Firm									1	1
Red		1								1
Edematous									1	
Tan										1
MANDIBULAR LYMPH NODE										
Enlarged	1	3	5	4	1		1	1	3	1
Tan							1		1	
Firm									1	
Dark red		3	3	3				1		1
Mass						1				
Contained red material				1						
Edematous									1	
MAMMARY GLAND										
Milk cyst						2				
Yellow			1							
Thickened/enlarged						1				1

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MAMMARY GLAND (continued)										
Mass									1	
THYMUS										
Enlarged	5	5	2	3	1			1		1
Firm	2	1	1		1					1
Tan	1									
Red	2	5	1	1	1			1		
Black focus			1							
Small			1		3					
Mass(es)										1
THYROID GLANDS										
Enlarged		1	2							
Red			1							
Mass			1							
Black focus										1

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THORACIC CAVITY										
Contained fluid, red/brown	2	2	2	4		1	1	2	1	1
Mass										1
Contained clear fluid		1	1	1					1	1
DIAPHRAGM										
Nodule(s)			1							
Mass(es)						1				1
HEART										
Enlarged	1		3	2	3					
White foci	1									
Tan/pale foci, diffuse			2	1	1					
Soft/flaccid			2			1		1	1	
Firm		1			1					
Red focus			1	1						1
Black foci				1						

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HEART - Auricles										
Enlarged	3	1	1	1	1	1		1		
Firm	2	1		2	1			1		2
Dark red	3	2		1	2					3
Black focus							1			
Nodules			1							
Tan				1	1			1		
LUNG										
Red/mottled red	10	10	12	9	11	4	5	2	5	10
Tan/yellow, focal/diffuse	2	1	1	3		1	1			
Mass									1	1
Nodules						1				
Black foci					1					
Mottled		1								
Soft								1		
Pale	1		2			1	1	2	3	1
Mottled brown				1						

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LARYNX										
Plugged with food									1	
LIVER										
Mottled red/red foci/red focus	7	3	7	4	2	3	4	7	4	6
Pale/tan/yellow, diffuse/multifocal	4	4	11	10	2		4	7	8	5
Enlarged	4	6	11	7	4	1	2	1	2	2
Lobulated	1	1	1	3		1		1	1	
Granular/pitted	6	8	8	8	1	1	2	5	4	4
Brown, diffuse/focal	4	6	5	6	2	2			1	
Nodule(s)		1	2	1	1		1			2
Mass(es)	2	1								
Cyst(s)				1						
Soft/spongy		1	1	3		2		2	3	2
Firm		2	2	2	1			1		1
HEPATIC LYMPH NODE										
Enlarged	2	1	2						1	
Tan	1		1							

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HEPATIC LYMPH NODE (continued)										
Red		1	1						1	
Nodules	1									
ADRENAL GLANDS										
Enlarged	1	2	3	3	4	3	2		1	1
Dark red/mottled red	1	1			1					
Tan	1		1		1					1
Brown			2	1	1				1	
SPLEEN										
Enlarged	10	12	14	14	4	3	7	7	7	11
Dark red/purple	5	6	6	4	4	3	2	2	3	2
Tan/yellow foci, focal	2	1	2	4			1		1	
Dark focus/black focus, diffuse						1				
White foci	1		1						1	
Nodule(s)	2		1				1			
Adhesions			2							2
Small					4					

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ORGAN Lesion (RDX Dose Levels: mg/kg/day)	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
SPLEEN (continued)										
Soft						1	1	1	1	
Mass(es)									1	
Granular/pitted	1		1							
Firm			1		1	1				1
Abscess										1
Cyst								1		
PANCREAS										
Red foci										1
Pale/tan/yellow			2					1	1	
Nodule(s)	1	1						1	1	
Mass(es)		1								
Enlarged		1								1
PANCREATIC LYMPH NODE										
Enlarged	3		1	2		2	1	1	2	
Red	1			2		1	1			

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KIDNEY										
Dark red	2	1		1			1			2
Brown	9	10	14	19	12	3	5	8	7	6
Yellow/tan		2	3		7					1
Black		2	2							
White/ gray foci			1	1	1					
Granular/pitted	1	1	6	2						
Enlarged/swollen		2			6					
Mass					1					
Thin cortex								1		
Small					2					
Dilated pelvis		2	1		8	1	1			1
Cyst			1							
Soft/flaccid					1	1				
Firm	1	2								
Nodule(s)	1	1					1			
URINARY BLADDER										
Distended with red fluid	1	2	1	3	15					

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URINARY BLADDER (continued)										
Mass		1							2	
Firm					1					
Thickened					2					
Distended with yellow fluid		2		4	3					
Dark red					1					
Nodule(s)			1	1						
TESTES										
Interstitial matter/mass - yellow/										
dark red/tan/white	11	15	17	20	11					
Enlarged	2	1	2	3						
Dark red foci	1	1	1		2					
Tan foci, diffuse	2		1	3	1					
Blue/gray focus	1		1	3	1					
Nodule(s)			2	1						
Soft/flaccid	2	6	11	8	8					
Small	7	10	14	13	13					
Gray/pale	1									

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EPIDIDYMIS										
Enlarged					1					
Nodules			2	1						
Mass	1			1						
SEMINAL VESICLES										
Enlarged		2			6					
Small			1		1					
Dark red		1	2		5					
Nodule(s)			1	1						
Firm					1					
Contained red fluid					2					
Gray		1			1					
PROSTATE										
Enlarged/swollen		3	1	1	12					
Small					1					
Dark red		1			4					
Mass		1								

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PROSTATE (continued)										
Nodule(s)			1	1						
Tan/gray		1			1					
Firm		1			3					
Contained dark red fluid										
PENIS										
Red discharge			1		1					
Firm					1					
Tan					1					
Crusted material - white	1									
Enlarged					1					
SCROTAL SAC										
Nodules	1			1						
OVARIES										
Red						1	1	1	1	
Cyst(s)									1	2

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OVARIES (continued)										
Brown						1				
Enlarged								1	1	1
Mass									1	
Gray									1	
UTERUS										
Distended/enlarged						2		1	1	5
Red focus (endometrium)						1		2	1	2
Mass						1	2		4	3
Nodule						1				
Contained red fluid						1				
Cyst									1	1
Black/darkened							1			1
Firm, focal/diffuse										3
VULVA										
Mass							1			
Discharge, brown						1				

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CERVIX										
Nodule										
VAGINA										
Red discharge										1
STOMACH										
Out-pocketing				1						
Firm					1					
Black focus				1						
Nodules				1						1
Contained yellow fluid	1									
Distended/gas filled		1								2
DUODENUM										
Gas filled/distended	1				1			1		1
Red focus	1				1					
Yellow				2						1
Black foci									1	

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DUODENUM (continued)										
Contained fluid - yellow/red									1	
Nodules				1						
JEJUNUM										
Gas filled	1		1		1					2
Red foci	1				1					
Contained material - yellow/red	1		1		1				1	
Yellow				2					1	1
Nodules				1						
ILEUM										
Gas filled	1		1		2					2
Contained red material					1			1		
Yellow				2						1
Red, focal/diffuse					1					
Nodules				1						

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CECUM										
Gas filled/distended/enlarged		1	1		3	1		1		
Yellow						1				
Red foci					2					
Contained fluid, brown, green		1	1		3	1				
Firm					3					
Nodules				1	1					

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COLON										
Gas filled	1		1		2					
Distended with green material		1								
Nodules				1	1					
RECTUM										
Gas filled					1					1
Mass									1	
Nodules				1						
MESENTERIC LYMPH NODE										
Dark red	1	2	3	3				1	3	1
Enlarged	5	5	5	7	1			1	2	3
Nodule(s)				1	1					
Firm										2
Tan				2						
MESENTERY										
Nodules	1		1	1					1	

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ABDOMINAL/MESENTERIC FAT										
Body/mass/nodule/necrosis	1	1	4	6	4		3		1	3
Yellow		1		1					1	2
ABDOMINAL CAVITY										
Contained fluid - dark red/brown/yellow	2		3	3	3	2			2	1
Mass				2		2		1		1
Nodule(s)	1		1	1						
Contained clear fluid			1	1	2					
EYE										
Missing									1	
White/opaque		1	1		2					1
Small	1		1		1					
Blackened										1
Flaccid/soft										1
Red crusted cornea			1							
Enlarged				1						
Red discharge	1									

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EYE (continued)										
Red			1		1		1			1
OPTIC CHIASMA										
Thin	1									
Gray	1									
BRAIN										
Indented ventral surface	2	2	5	1		3	6	4	3	3
Soft/flaccid	2	1	1			2	1	1	1	
Black/blue foci			1	1						
Dark red foci	1				2		1	1		
BRAIN/MENINGES										
Covered with red material	1	1			1					
OLFACTORY BULB										
Red focus	1									

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PITUITARY GLAND										
Enlarged/mass	3	4	6	2		6	7	5	11	7
Dark red, diffuse/multifocal	4	1	6	2		6	7	4	10	6
Tan/gray									1	1
Mottled brown									1	
White focus							1	1	1	
Black			1							
Nodule			1					2		
Soft	1									
Firm			1							
EAR										
Nodule		1								
TAIL										
Red area					1					2
Fighting wounds	1				1					
Crusted										2
Black					1					1

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Moribund Sacrifices and
Spontaneous Deaths

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
VENTRAL SKULL										
Contained red material						1				
NOSE										
Red discharge					3	1				
MANDIBLE										
Mass						1				
AXILLARY LYMPH NODE										
Mass										1
Enlarged	2		1	1						
Dark red			1	1						
CERVICAL LYMPH NODE										
Enlarged	1		1		1					1
Red			1							

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Moribund Sacrifices and
Spontaneous Deaths

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
LUMBAR LYMPH NODE										
Enlarged	3	3	1	2	2		1		1	3
Red			1							1
Tan				2						
Firm										1
PERIRENAL AREA										
Edema					1					
INGUINAL LYMPH NODE										
Enlarged	1		1							
Dark red			1							
RESPIRATORY/MEDIASTINAL LYMPH NODE										
Enlarged	4	3	4	1	1	1	2		3	
Tan							1		1	
Red		1	1			1	1			

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Terminal Sacrifice and
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Fischer 344 Rats

NECROPSY OBSERVATIONS
Moribund Sacrifices and
Spontaneous Deaths

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
PELVIC CAVITY										
Mass				1						
PELVIC LYMPH NODE										
Enlarged										
RENAL LYMPH NODE										
Enlarged	1	5	1	1		1				3
Brown/tan				2						
Red		4	1	1		1				1
Firm										1
BONE MARROW										
Dry									1	
Not evident							1			
Pale									1	
TEETH										
Overgrown						1				

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Terminal Sacrifice and
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Fischer 344 Rats

NECROPSY OBSERVATIONS
Moribund Sacrifices and
Spontaneous Deaths

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
LIP										
Nodule	1									
HIND LIMB										
Mass - intramuscular										1
Missing toes					1					
URETERS										
Distended		1								
GENERALIZED LESIONS										
Yellow discolorations			2							
ANAL LYMPH NODE										
Enlarged				1						
Brown				1						

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
Number of Rats Examined	38	36	25	29	4	43	46	42	42	28
No Gross Lesions	0	0	0	0	0	0	2	0	0	0
SKIN/Subcutis										
Yellow discoloration - generalized		1								
Mass(es)	6	11	7	8	1	9	15	13	9	7
Abscess				1						
Nodule(s)	2			1						
Thickened/enlarged										1
Hairloss			1						1	2
Cyst		1				1				1
Ulcer			1							
Black focus	1									
Erosion							1			
Necrosis						1				
Firm focus/foci	2									
Crusted/red crusted	2	1								

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
THYROID GLANDS										
Enlarged		1	2	1		1		3	1	
Red				1	1	1		3		
Mass				2						
THORACIC CAVITY										
Contained fluid, red/brown	1									
Contained clear fluid				1						
HEART										
Enlarged										
Dilated ventricles	1									
Tan/pale foci, diffuse			2			1				
Soft/flaccid										
Nodule(s)	1									1
HEART - Auricles										
Firm										
Dark red										

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
SKIN Around the Eyes										
Crusted red material/red discharge	2		1	1	1	2	6	2	3	
Black matter										
MANDIBULAR SALIVARY GLAND										
Enlarged										1
MANDIBULAR LYMPH NODE										
Enlarged	2		1	1			1			5
Tan	1									
Firm	1									
Dark red							1			2
MAMMARY GLAND										
Milk cyst	4	1		1		7	9	4	6	3
Thickened/enlarged						2	1	1		
THYMUS										
Enlarged	1									
Brown			1							

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
HEART - Auricles (continued)										
Nodules			1					1		1
LUNG										
Red/mottled red	2	5	3	4		3		2		1
Tan/yellow, focal/diffuse	1			1		1		1		
White/gray foci	2									
Nodules									1	
Pale	1	2	1					1	1	
LIVER										
Mottled red/red foci/red focus	15	17	11	19	1	11	9	14	15	5
Pale/tan/yellow, diffuse/multifocal	16	14	4	9		17	16	19	17	12
Enlarged	11	8	4	5	1	1		1	1	1
Granular/pitted	8	9	4	4		5	1	3	3	1
Brown, diffuse/focal	2		2	1		1	2	2	1	1
Pinpoint foci		1	1		1	3				1
Nodule(s)	2	3	2	5		10	3	8	5	5
Mass(es)	1	1		3		1	3	1	1	2

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
LIVER (continued)										
Black focus									1	
HEPATIC LYMPH NODE										
Enlarged	2	1	3	1						
Tan	2		1	1						
Firm	1		1							
Red			2							
Soft		1								
ADRENAL GLANDS										
Enlarged	3	2	6	4		4	2	4	1	1
Dark red/mottled red	1	1	1	2				3	1	
Black focus	1					1				
Brown	1		1	1		2				1
Soft						1				
Mass	1		1	1						
Nodule(s)				1						

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
SPLEEN										
Enlarged	23	24	16	16	2	9	3	4	5	8
Dark red/purple	3	4	1	2					1	2
Tan/yellow foci, focal	5	3	4	2		1		1	1	1
Dark focus/black focus, diffuse		1							1	
Nodule(s)	1	1	1					1		
Small							1			
Soft	1									
Pale								1		1
PANCREAS										
Brown	2					1				
Red foci		1								
Pale/tan/yellow			1							
Edematous				1						
Nodule(s)						1			1	

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
PANCREATIC LYMPH NODE										
Enlarged		1	1	1		1				
Red			1	1		1				
KIDNEY										
Dark red		1		1		1	1			
Brown	29	33	22	27	4	29	31	25	28	21
Yellow/tan	4	1				1			1	
Granular/pitted	10	12	6	7		1		1	1	
Enlarged/swollen	1	1								
Dilated pelvis										
Cyst				1			1		1	2
Soft/flaccid						1				
Nodule(s)									1	
URINARY BLADDER										
Distended with red fluid										1
Mass										
Distended with yellow fluid				1						

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion / RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
TESTES										
Interstitial matter/mass, yellow/ dark										
red/tan/white	34	35	23	27	4					
Enlarged										
Dark red foci	1									
Blue focus	1			3						
Nodule(s)		2	1	2	1					
Firm				2						
Soft/flaccid	4	9	6	5						
Cyst	1									
Small	4	12	4	4	2					
EPIDIDYMIS										
Tan	1									
Enlarged	1									
Nodules		2								
Abscess					1					

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
SEMINAL VESICLES										
Small		2	1							
PROSTATE										
Enlarged/swollen		1								
Small		2	1							
Dark red										
Firm		1								
Contained dark red fluid										
Green		1								
PENIS										
Mass		1	1							
Tan										
SCROTAL SAC										
Nodules		3								

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
OVARIES										
Cyst(s)						2			1	
Enlarged						1				1
Nodule									1	
UTERUS										
Distended/enlarged						4	4	8	5	2
Red focus (endometrium)						1		1		3
Contained clear fluid						1				
Mass						7	6	7	8	6
Nodule						1	1	1	2	
Cyst							1			2
Firm, focal/diffuse										1
VULVA										
Mass										
CERVIX										
Nodule										

L06121 SN 6
Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
STOMACH										
Dark red foci			1			1		1		
Thickened			1							
Soft tissue in lumen								1		
DUODENUM										
Gas filled/distended	1	1								
Thickened		1								
Red focus		1								
Contained fluid - yellow/red			1							
JEJUNUM										
Contained material - yellow/red			1							
ILEUM										
Contained red material			1							

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Terminal Sacrifice and
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Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
CECUM										
Gas filled/distended/enlarged			1							
Thickened			1							
Contained fluid, brown/green/red			1							
Firm										
MESENTERIC LYMPH NODE										
Dark red	1		1	1					1	
Enlarged	3	1	1	1					1	
Nodule(s)		1								
Firm	1									
Tan	1									
COLON										
Distended with gas									1	

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
MESENTERY										
Blood vessels enlarged/dark red			1							
ABDOMINAL/MESENTERIC FAT										
Body/mass/nodule/necrosis	10	2	3	8	2	4	5	3	5	3
Nodule(s)		1								
Cyst(s)	1									
ABDOMINAL CAVITY										
Contained fluid, dark red/brown/yellow		1	1				1		1	1
Nodule(s)		1								
EYE										
Missing	1					2	1		1	
White/opaque	4		1			3	2	3	1	9
Small	1					1		1	1	4
Flaccid/soft									1	
Cornea not evident								1		
Red crusted cornea	2	2			1	2			1	1

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
EYE (continued)										
Enlarged			1			2				4
Red discharge		1				1	1	2		
Red										4
OPTIC CHIASMA										
Thin	2					2		1	1	
Gray	2					2		1	1	
BRAIN										
Indented ventral surface			1				3			
Soft/flaccid			2				4			
Dark red foci				1						
Tan										
Mass							1			
PITUITARY GLAND										
Enlarged/mass	4	8	4	6		11	27	13	22	8

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Terminal Sacrifice and
Deaths 12-24 Months
Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
PITUITARY GLAND (continued)										
Dark red, diffuse/multifocal	8	13	6	4		23	29	28	22	14
Tan/gray	1						1		2	1
Mottled brown	1						1		1	
White focus		1								
Cyst								1		
TAIL										
Mass	2	1								1
Nodule		1								
Red area					1					
Fighting wounds					1					
Crusted										
Black										
VENTRAL SKULL										
Contained red material							1			

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Terminal Sacrifice and
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Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
NOSE										
Red discharge										
CERVICAL LYMPH NODE										
Enlarged			1							
Tan										
LUMBAR LYMPH NODE										
Enlarged						1				
RESPIRATORY/MEDIASTINAL LYMPH NODE										
Enlarged	1	1								1
Tan/grey	1	1								
PELVIC LYMPH NODE										
Enlarged										1
RENAL LYMPH NODE										
Enlarged		1	2				1			

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Fischer 344 Rats

NECROPSY OBSERVATIONS
Terminal Sacrifice
(Scheduled Sacrifice)

ORGAN Lesion — RDX Dose Levels: mg/kg/day	MALES 0.0	MALES 0.3	MALES 1.5	MALES 8.0	MALES 40.0	FEMALES 0.0	FEMALES 0.3	FEMALES 1.5	FEMALES 8.0	FEMALES 40.0
RENAL LYMPH NODE (continued)										
Brown/tan			2							
Soft			1							
BONE MARROW										
Dry							2	1	1	
Not evident						1		2		1
TEETH										
Overgrown	1									
GENERALIZED LESIONS										
Enlarged lymph nodes							1			
VERTEBRA										
Thickened								1		

FINAL HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

SEPTEMBER 15, 1983

IITRI PROJECT NUMBER L06121
STUDY NUMBER 6

Donovan E. Gordon, D.V.M., Ph.D.
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of Veterinary Pathologists

FINAL HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

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IITRI Project Number L06121, Study Number 6
Sponsor Project Number DAMD 17-79-c-9161

Report of Histopathologic Findings

Methods

In accordance with the amended experimental protocol, a histopathologic examination by light microscopy was conducted on hemotoxylin-eosin (H&E) stained tissue sections from 331 (132 male, 199 female) Fischer 344 rats sacrificed at the conclusion of the 24-month chronic toxicity/carcinogenicity study of hexahydro -1,3,5-trinitro-1,3,5-triazine (RDX). In addition, tissues from 182 (116 male, 66 female) rats which either died spontaneously or were sacrificed as moribund during the 12 to 24 month study period were also examined. The distribution of the rats by group and sex is indicated in the table below. Each group was fed either RDX as a dietary admixture or a control diet until death or sacrifice and then subjected to a extensive necropsy examination. The necropsy of animals, collection and fixation of tissue specimens, and preparation of stained tissue sections were conducted by IIT Research Institute.

The experimental design of the study, as it relates to the histopathologic evaluation, is also outlined below:

Treatment Group	Treatment	Number of Males		Number of Females		Dose Level mg/kg/day
		TS*	SDMS**	TS	SDMS	
I	---	38	17	43	10	0.0
II	RDX	36	19	45	10	0.3
III	RDX	25	27	42	12	1.5
IV	RDX	29	26	41	14	8.0
V	RDX	4	27	28	20	40.0

*terminal sacrifice **spontaneous death/moribund sacrifice

Tissues from animals of the various experimental groups were examined according to Level I (extensive; all animals in the RDX 0.0 mg/kg/day and RDX 40.0 mg/kg/day groups) or Level II (partial; all animals in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day and RDX 8.0 mg/kg/day groups) designations as specified in the experimental protocol.

The "Pathology Report" forms and appendices which accompany this report constitute an accountability of all tissues examined in accordance with the experimental protocol. The grading system and abbreviations used on the "Pathology Report" forms and in the tables are as follows:

Grade 1 = minimal severity	N = within normal limits
Grade 2 = mild severity	L = lesion present
Grade 3 = moderate severity	M = tissue not present
Grade 4 = marked severity	I = tissue section inadequate
P = present, no grade	- = not applicable

The incidences of microscopic lesions are summarized by group and sex in the Pathology Appendices as follows:

Pathology Appendix A: Incidence of Lesions Considered to be Treatment Related
Pathology Appendix B: Cause of Death Table
Pathology Appendix C: Lesion Incidence Comparison Table - Males
Pathology Appendix D: Histopathology Lesion Severity and Incidence Table - Males
Pathology Appendix E: Lesion Incidence Comparison Table - Females
Pathology Appendix F: Histopathology Lesions Severity and Incidence Table - Females

Results

Primary, treatment-related, toxicologically significant microscopic lesions were confined to the spleen and urogenital system (kidney, urinary bladder) of males and the eye of females. These lesions involved both Terminal Sacrifice (TS) and 12 to 24 month Spontaneous Death/Moribund Sacrifice (SDMS) rats. The splenic and urogenital lesions increased in severity and incidence with increasing RDX dosage and were present in males of all groups receiving RDX. The ocular lesions observed in females could not be fully evaluated in the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups since eye was not routinely examined for these groups. This precluded determination of a dose-response relationship and no-effect level for these lesions. Following is a description of all treatment-related lesions observed in this phase of the study.

Spleen (primary lesion)

A dose-related, minimal to moderate, diffuse increase of yellowish-brown granular pigment, resembling hemosiderin pigment, was observed in the red pulp of test males in the RDX 1.5

mg/kg/day, RDX 8.0 mg/kg/day, and RDX 40.0 mg/kg/day groups. The incidence of this lesion in TS/SDMS males was:

Group	I	II	III	I	V
Incidence of increased pigment	3/55 (6%)	1/52 (2%)	11/52 (21%)	15/55 (27%)	18/31 (58%)

Kidneys and Urinary Bladder (primary lesions)

Unilateral or bilateral necrosis of the renal medullary papilla was present in SDMS RDX 40.0 mg/kg/day rats (18/27, 67%) An associated luminal urinary bladder distention (24/27, 89%) and a hemorrhagic and/or suppurative cystitis (18/27, 67%) was observed. Luminal distention of the bladder, without renal necrosis and cystitis was also observed in one TS male from this group. One RDX 0.3 mg/kg/day SDMS male (#151, 80-6658) had concurrent lesions of renal necrosis, bladder distention, and cystitis. These lesions were multifocal to diffuse in distribution. The cystitis was minimal to marked in severity and the more severe lesions were usually accompanied by serosal inflammation of the bladder wall and peritonitis. The peritonitis probably resulted from leakage of urine into the peritoneal cavity or rupture of the bladder. Dilatation of the renal pelvis and/or ureter(s) were also noted among these animals, however, these lesions were not fully evaluated or graded since the plane of section through the kidneys was variable and visualization of these structures was often precluded. Lesions of bladder distention and/or cystitis were also observed among a few TS/SDMS males from the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups following microscopic examination of grossly visible lesions involving the urinary bladder. Otherwise, urinary bladder was not routinely examined in these groups.

Urogenital System (secondary lesions)

A large spectrum of secondary lesions involving the urogenital system of SDMS RDX 40.0 mg/kg/day males was also observed. These were associated with renal papillary necrosis, bladder distention, and cystitis and included mineralization of renal tissue (blood vessels, tubular basement membranes, and tubular epithelial cells)(13/27), uremic mineralization of the bladder wall (1/27), ascending pyelonephritis with bacterial emboli in blood vessels (1/27), suppurative pyelitis (5/27), suppurative inflammation of the prostate (19/27) and seminal vesicles (8/27), and distention of ducts in the seminal vesicles with secretions (19/27). Lesions of suppurative prostatitis were also present in TS/SDMS males of the RDX 0.3 mg/kg/day (4/55), RDX 1.5 mg/kg/day (9/52), and RDX 8.0 mg/kg/day (12/55) groups. Treatment-related lesions consisting of renal and bladder

mineralization, pyelonephritis, pyelitis, renal bacteremia, and distention of seminal vesicle ducts with secretions were also present among a few TS/SDMS males from these groups.

Parathyroid (secondary lesion)

Minimal to moderate diffuse parathyroid hyperplasia was present among SDMS RDX 40.0 mg/kg/day males (12/27) and in one TS RDX 40.0 mg/kg/day male. If symmetry could be evaluated (both glands present), the hyperplasia was usually bilateral. Often renal papillary necrosis and parenchymal mineralization involving the kidney, stomach, and heart was also present. This correlation of parathyroid hyperplasia and mineralization indicated that the hyperplasia was a secondary response associated with uremia rather than primary (initial) lesion. Two TS RDX 0.0 mg/kg/day males (controls) exhibited unilateral or bilateral diffuse parathyroid hyperplasia. This low incidence was considered within the normal background range of this lesion.

Lung (secondary lesion)

Mild uremic mineralization involving the alveolar septa and blood vessels was present in the lung of one SDMS RDX 40.0 mg/kg/day male (#662, 80-7169) and was accompanied by parenchymal mineralization of the kidneys, heart and stomach.

Heart (secondary lesion)

Minimal to moderate uremic mineralization involving the blood vessel walls and/or myocardial fibers was present in the heart of a few SDMS RDX 40.0 mg/kg/day males (6/27) and a single SDMS RDX 0.3 mg/kg/day male (#151, 80-6658). They were accompanied by similar mineralization in the kidney and/or stomach of these animals.

Stomach (secondary lesion)

Minimal to mild uremic mineralization of the blood vessel walls and/or the glandular mucosa was present in the stomach of some of the SDMS RDX 40.0 mg/kg/day males (12/27). It was often accompanied by similar mineralization in the kidneys and/or heart of these animals. One TS RDX 0.0 mg/kg/day (control) male had uremic mineralization of the stomach and other tissues as well as generalized lesions of monocytic leukemia.

Eyes (primary lesion)

There was an increased incidence of unilateral and bilateral lenticular cataracts in TS/SDMS RDX 40.0 mg/kg/day females when compared with concurrent controls. This microscopic lesion could be correlated with an increased incidence of grossly visible ocular opacities as reported at necropsy of these

animals. The incidence of cataracts among the RDX 0.0 mg/kg/day and 40.0 mg/kg/day group animals was:

Group	Unilateral Lesion	Bilateral Lesion	Combined
Control	11/53 (20%)	4/53 (8%)	15/53 (28%)
40.0 mg/kg/day	16/48 (33%)	16/48 (33%)	32/48 (67%)

The cataracts were confined to the cortex of the lens in all affected animals. This lesion was also accompanied by unilateral or bilateral lesions of retinal degeneration (RD) and/or lens induced inflammation (LII) of the intraocular tissues in approximately 66% of these control and test animals. However, when the incidence of RD and LII among animals with cataracts were examined separately, the incidence of LII was significantly greater among the TS/SDMS RDX 40.0 mg/kg/day females as shown below:

Group	RD Incidence*	LII Incidence*
Control	9/15 (60%)	1/15 (6.7%)
40.0 mg/kg/day	12/32 (37.5%)	11/32 (34.4%)

* combined TS and SDMS

The LII appeared to represent progression of the cataractogenic change in the lens resulting in rupture of the lens capsule and extrusion of lenticular debris into the adjacent aqueous and vitrious humor. This material is irritating and probably induced the chronic intraocular inflammatory reaction which involved the retina and adjacent tissues of the anterior and posterior uveal tract.

Other Observations

With the exception of the above lesions, summarized in Pathology Appendix A, the remainder of the microscopic lesions observed among control (RDX 0.0 mg/kg/day) and RDX receiving test animals were ascribed to naturally occurring degenerative, inflammatory, proliferative, and neoplastic processes. The majority of these changes have been previously reported as spontaneous lesions in this strain of rat (see references).

Cause of Death Summary

A treatment-related increase in morbidity and mortality was evident among males of the RDX 40.0 mg/kg/day group. This was ascribed to renal medullary necrosis, uremia, and/or urogenital tract obstruction with secondary inflammation. Spontaneous neoplastic disease was the major cause of death among males in the remaining groups and in females from all groups. The probable cause of death or morbidity is tabulated, by experimental group and sex, below:

MALES

Cause of Morbidity or Death / Group	I	II	III	IV	V
Number SDMS	(17)	(19)	(27)	(26)	(27)
Neoplastic disease	16	15	22	17	2
Neoplastic disease, uremia			1		
Neoplastic disease, urogenital inflammation		1	1	6	
Neoplastic disease, urogenital obstruction				1	2
Neoplastic disease, urogenital obstruction and inflammation			1		2
Neoplastic disease, renal disease, uremia					1
Uremia, urogenital obstruction, and inflammation					1
Renal disease, urogenital obstruction, and inflammation					1
Renal necrosis, urogenital obstruction, and inflammation					3
Renal necrosis, uremia, urogenital obstruction, and inflammation					14
Undetermined		2		2	1

FEMALES

Cause of Morbidity or Death / Group	I	II	III	IV	V
Number SDMS	(9)	(10)	(12)	(14)	(20)
Neoplastic disease	9	10	12	14	20
Undetermined	1				

Discussion

Primary urogenital lesions consisting of renal medullary necrosis, bladder distention, and cystitis were confined primarily to the SDMS RDX 40.0 mg/kg/day males in this phase of the study. These lesions were also present on one SDMS RDX 0.3 mg/kg/day male. These lesions were similar in appearance to those previously reported (12-Month interim Histopathology Report) among males of the RDX 40.0 mg/kg/day group that either died or were sacrificed moribund during test months 6-12 of this study. The above lesions are indicative of urinary stasis due to partial or complete blockage of the urethra, however, the location and exact cause of the urethral obstruction was not determined. In addition, the pathogenesis of these lesions was not established. It is not clear whether the renal necrosis occurred first with subsequent urethral blockage and urinary bladder involvement, or whether urinary bladder changes occurred first followed by blockage and retrograde involvement of the kidney, or whether the kidney and urinary bladder were affected simultaneously. Neither was the sequence of involvement of the prostate and seminal vesicle clear. The inflammatory changes in these tissues probably resulted from retrograde involvement following urinary stasis. Likewise, leakage of urine from the distended urinary bladder into the peritoneal cavity was the probable cause of the peritonitis. Regardless of the sequence of events, the renal injury caused a series of subsequent metabolic and morphologic changes involving the parathyroid glands that is consistent with renal or secondary hyperparathyroidism. In this syndrome, the kidney is unable to hydroxylate 25-hydroxycholecalciferol to 1,25-dihydroxy-cholecalciferol (active form of vitamin D) resulting in lowered calcium absorption in the intestine. This, in turn, results in lowered serum calcium levels which stimulates the parathyroid gland, seen microscopically as hyperplasia, to produce parathormone (PTH) for mobilization of calcium from the bone. In the end stages of renal disease, the kidney is unable to secrete phosphate ion, causing a hyper phosphatemia which leads to further hypocalcemia and parathyroid stimulation since the serum ion concentrations of phosphate and calcium are inversely related. Since the excess calcium resorbed due to PTH secretion cannot remain in the blood, it is deposited in soft tissues throughout the body and is visualized microscopically as uremic mineralization in the heart, stomach, lung, and urinary bladder. The absence of similar changes in urogenital of males examined at the 6 month interval may indicate that a latent period is required before RDX induced changes are manifested.

Summary and Conclusions

Compound related lesions observed among the TS animals and SDMS animals of test months 12 to 24 were confined to the spleen of the RDX 1.5 mg/kg/day, RDX 8.0mg/kg/day, and RDX 40.0 mg/kg/day males; urogenital tract of the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, RDX 8.0 mg/kg/day, and RDX 40.0 mg/kg/day males; and eyes of the RDX 40.0 mg/kg/day females. The urogenital lesions were the cause of death or moribund sacrifice among a significant number of RDX 8.0 mg/kg/day and RDX 40.0 mg/kg/day males.

Based on the present data, a no-effect level of RDX was not reached after 24 months of dietary administration to male rats. The maximum no-effect level of RDX in females was not established with respect to the ocular lesion.

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PATHOLOGY APPENDIX A

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

L06121 SN6
FINAL REPORT

MALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
SPLEEN	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Increased pigment	0/38	3/17	0/36	1/19	7/25	4/27	11/29	4/26	0/4	18/27
PROSTATE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Inflammation, suppurative	0/38	2/16	1/36	3/19	2/25	7/27	4/29	8/26	0/4	19/27
SEMINAL VESICLE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Inflammation, suppurative	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	8/27
Distended with secretion	0/38	0/16	0/36	1/19	0/25	0/27	0/29	0/26	1/4	18/27
URINARY BLADDER	(38)	(16)	-	(6)	-	(3)	(2)	(4)	(4)	(27)
Cystitis, suppurative	0/38	0/16	-	0/6	-	0/3	1/2	0/4	0/4	0/27
Cystitis, hemorrhagic-suppurative	0/38	0/16	-	2/6	-	1/3	0/2	0/4	0/4	17/27
Cystitis, hemorrhagic	0/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	1/27
Mineralization, uremic	0/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	1/27
Distention, luminal	0/38	0/16	-	2/6	-	1/3	0/2	3/4	1/4	23/27
LUNG-MAINSTEM BRONCHI	(38)	(17)	(5)	(10)	(4)	(13)	(5)	(11)	(4)	(27)
Mineralization, alveolar	0/38	0/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	1/27

Code: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable (—) = number of animals for which tissue was represented

L06121 SN6
FINAL REPORT

MALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
PARATHYROID	(37)	(17)	-	-	-	-	-	-	(4)	(27
Hyperplasia	2/37	0/17	-	-	-	-	-	-	1/4	11/2
HEART	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27
Mineralization, vessels, uremic	0/38	0/17	0/36	1/19	0/25	1/27	0/29	0/26	0/4	6/27
Mineralization, myocardial, uremic	0/38	0/17	0/36	1/19	0/25	1/27	0/29	0/26	0/4	2/27
KIDNEY	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Pyelonephritis	0/38	0/17	0/36	0/19	0/25	2/27	1/29	1/26	0/4	1/27
Pyelitis, suppurative	0/38	0/17	0/36	1/19	0/25	0/27	0/29	1/26	0/4	5/27
Necrosis, medullary papilla	0/38	0/17	0/36	1/19	0/25	0/27	0/29	0/26	0/4	18/27
Mineralization, uremic	1/38	0/17	0/36	1/19	0/25	2/27	0/29	0/26	0/4	13/27
Bacteremia	0/38	0/17	0/36	0/19	0/25	1/27	0/29	0/26	0/4	1/27
STOMACH	(38)	(17)	-	(1)	(1)	(4)	-	(6)	(4)	(27)
Mineralization, uremic	1/38	0/17	-	0/1	0/1	0/4	-	0/6	0/4	12/27
URETER	-	-	-	(1)	-	-	-	-	-	-
Dilatation	-	-	-	1/1	-	-	-	-	-	-
Peritonitis	-	-	-	1/1	-	-	-	-	-	-

: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL REPORT

FEMALE F344 RATS

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
EYE	(43)	(10)	(3)	(1)	(6)	-	(3)	-	(28)	(20)
Lens, cataract	14/43	1/10	2/3	0/1	4/6	-	0/3	-	23/28	9/20
Lens-induced inflammation	0/43	1/10	0/3	0/1	1/6	-	0/3	-	9/28	2/20
Degeneration, retinal	11/43	0/10	1/3	0/1	4/6	-	0/3	-	10/28	2/20

ode: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

PATHOLOGY APPENDIX B

CAUSE OF DEATH TABLE

CAUSE OF DEATH TABLE

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
I	M	80-6508	Neoplastic disease*
I	M	80-6511	Neoplastic disease
I	M	80-5614	Neoplastic disease*
I	M	80-6515	Neoplastic disease*
I	M	80-6533	Neoplastic disease*
I	M	80-6535	Neoplastic disease*
I	M	80-6536	Neoplastic disease*
I	M	80-6547	Neoplastic disease*
I	M	80-6548	Neoplastic disease
I	M	80-6549	Neoplastic disease*
I	M	80-6558	Neoplastic disease
I	M	80-6561	Neoplastic disease
I	M	80-6562	Neoplastic disease
I	M	80-6563	Neoplastic disease*
I	M	80-6567	Undetermined
I	M	80-6570	Neoplastic disease
I	M	80-6575	Neoplastic disease*
I	F	80-6589	Neoplastic disease
I	F	80-6604	Neoplastic disease*
I	F	80-6605	Neoplastic disease
I	F	80-6617	Neoplastic disease*
I	F	80-6619	Neoplastic disease
I	F	80-6620	Neoplastic disease*
I	F	80-6625	Neoplastic disease*
I	F	80-6632	Neoplastic disease*
I	F	80-6635	Undetermined
I	F	80-6649	Neoplastic disease*
II	M	80-6658	Renal necrosis, uremia, urogenital obstruction and inflammation
II	M	80-6663	Neoplastic disease
II	M	80-6666	Neoplastic disease
II	M	80-6672	Neoplastic disease
II	M	80-6676	Neoplastic disease*
II	M	80-6680	Neoplastic disease
II	M	80-6687	Neoplastic disease, urogenital inflammation*
II	M	80-6692	Neoplastic disease
II	M	80-6700	Neoplastic disease
II	M	80-6703	Neoplastic disease
II	M	80-6796	Undetermined*
II	M	80-6712	Neoplastic disease*
II	M	80-6717	Neoplastic disease
II	M	80-6718	Neoplastic disease*
II	M	80-6720	Neoplastic disease*

CAUSE OF DEATH TABLE

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
II	M	80-6721	Neoplastic disease
II	M	80-6724	Neoplastic disease*
II	M	80-6729	Undetermined
II	M	80-6732	Neoplastic disease
II	F	80-6744	Neoplastic disease*
II	F	80-6752	Neoplastic disease
II	F	80-6761	Neoplastic disease*
II	F	80-6777	Neoplastic disease*
II	F	80-6738	Neoplastic disease*
II	F	80-6749	Neoplastic disease*
II	F	80-6771	Neoplastic disease
II	F	80-6776	Neoplastic disease
II	F	80-6800	Neoplastic disease
II	F	80-6802	Neoplastic disease*
III	M	80-6813	Neoplastic disease
III	M	80-6816	Neoplastic disease*
III	M	80-6818	Neoplastic disease
III	M	80-6819	Neoplastic disease, uremia
III	M	80-6821	Neoplastic disease
III	M	80-6825	Neoplastic disease
III	M	80-6826	Neoplastic disease*
III	M	80-6831	Neoplastic disease
III	M	80-6835	Neoplastic disease
III	M	80-6840	Undetermined
III	M	80-6844	Neoplastic disease*
III	M	80-6845	Neoplastic disease
III	M	80-6846	Neoplastic disease, urogenital inflammation*
III	M	80-6849	Neoplastic disease
III	M	80-6850	Urogenital obstruction and inflammation
III	M	80-6852	Neoplastic disease
III	M	80-6855	Undetermined*
III	M	80-6857	Neoplastic disease
III	M	80-6859	Neoplastic disease*
III	M	80-6861	Neoplastic disease*
III	M	80-6864	Neoplastic disease
III	M	80-6866	Neoplastic disease*
III	M	80-6867	Neoplastic disease*
III	M	80-6868	Neoplastic disease*
III	M	80-6878	Neoplastic disease*
III	M	80-6880	Neoplastic disease*
III	M	80-6881	Neoplastic disease
III	F	80-6886	Neoplastic disease*
III	F	80-6890	Neoplastic disease

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
III	F	80-6893	Neoplastic disease*
III	F	80-6900	Neoplastic disease*
III	F	80-6903	Neoplastic disease
III	F	80-6911	Neoplastic disease*
III	F	80-6912	Neoplastic disease*
III	F	80-6917	Neoplastic disease
III	F	80-6928	Neoplastic disease*
III	F	80-6930	Neoplastic disease*
III	F	80-6936	Neoplastic disease*
III	F	80-6955	Neoplastic disease
IV	M	80-6961	Neoplastic disease, urogenital inflammation
IV	M	80-6965	Neoplastic disease
IV	M	80-6966	Neoplastic disease*
IV	M	80-6970	Neoplastic disease
IV	M	80-6972	Neoplastic disease*
IV	M	80-6974	Neoplastic disease*
IV	M	80-6977	Neoplastic disease*
IV	M	80-6979	Neoplastic disease
IV	M	80-6981	Undetermined
IV	M	80-6982	Neoplastic disease*
IV	M	80-6984	Neoplastic disease, urogenital inflammation*
IV	M	80-6985	Neoplastic disease, urogenital inflammation
IV	M	80-6990	Neoplastic disease, urogenital obstruction
IV	M	80-7000	Neoplastic disease*
IV	M	80-7001	Neoplastic disease*
IV	M	80-7002	Neoplastic disease*
IV	M	80-7005	Neoplastic disease, urogenital inflammation*
IV	M	80-7010	Neoplastic disease*
IV	M	80-7012	Undetermined*
IV	M	80-7013	Neoplastic disease*
IV	M	80-7020	Neoplastic disease*
IV	M	80-7021	Neoplastic disease
IV	M	80-7024	Neoplastic disease, urogenital inflammation*
IV	M	80-7025	Neoplastic disease, urogenital inflammation?
IV	M	80-7026	Neoplastic disease
IV	M	80-7028	Neoplastic disease*
IV	F	80-7036	Neoplastic disease*
IV	F	80-7053	Neoplastic disease*

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
IV	F	80-7059	Neoplastic disease*
IV	F	80-7071	Neoplastic disease*
IV	F	80-7074	Neoplastic disease
IV	F	80-7076	Neoplastic disease
IV	F	80-7077	Neoplastic disease*
IV	F	80-7082	Neoplastic disease
IV	F	80-7084	Neoplastic disease*
IV	F	80-7085	Neoplastic disease
IV	F	80-7089	Neoplastic disease
IV	F	80-7099	Neoplastic disease*
IV	F	80-7103	Neoplastic disease
IV	F	80-7105	Neoplastic disease
V	M	80-7109	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7113	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7117	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7118	Renal necrosis, uremia, urogenital obstruction and inflammation
V	M	80-7124	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7125	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7130	Renal necrosis, urogenital obstruction and inflammation*
V	M	80-7131	Renal necrosis, urogenital obstruction and inflammation
V	M	80-7134	Neoplastic disease
V	M	80-7137	Uremia, urogenital obstruction and inflammation
V	M	80-7140	Undetermined*
V	M	80-7144	Renal necrosis, uremia, urogenital obstruction and inflammation*

CAUSE OF DEATH TABLE

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
V	M	80-7146	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7153	Renal necrosis, urogenital obstruction and inflammation
V	M	80-7154	Neoplastic disease*
V	M	80-7157	Renal necrosis, uremia, urogenital obstruction and inflammation
V	M	80-7158	Renal disease, urogenital obstruction and inflammation
V	M	80-7160	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7161	Neoplastic disease, urogenital obstruction*
V	M	80-7162	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7163	Renal necrosis, uremia, urogenital obstruction and inflammation
V	M	80-7167	Neoplastic disease, renal disease, uremia
V	M	80-7169	Renal necrosis, uremia, urogenital obstruction and inflammation*
V	M	80-7172	Neoplastic disease, urogenital obstruction
V	M	80-7177	Neoplastic disease, urogenital obstruction and inflammation
V	M	80-7179	Neoplastic disease, urogenital obstruction and inflammation
V	M	80-7180	Renal necrosis, uremia, urogenital obstruction and inflammation
V	F	80-7184	Neoplastic disease
V	F	80-7188	Neoplastic disease*
V	F	80-7194	Neoplastic disease
V	F	80-7198	Neoplastic disease*
V	F	80-7208	Neoplastic disease*
V	F	80-7209	Neoplastic disease*
V	F	80-7210	Neoplastic disease
V	F	80-7211	Neoplastic disease*

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NOT INCLUDED
IN PAGINATION

FINAL HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

VOLUME 2
(PAGES 24 TO 122)

CAUSE OF DEATH TABLE

Group	Sex	Accession Number	Probable Cause of Morbidity(*)/Death
V	F	80-7212	Neoplastic disease*
V	F	80-7215	Neoplastic disease*
V	F	80-7292	Neoplastic disease*
V	F	80-7223	Neoplastic disease
V	F	80-7227	Neoplastic disease
V	F	80-7228	Neoplastic disease
V	F	80-7234	Neoplastic disease*
V	F	80-7235	Neoplastic disease
V	F	80-7239	Neoplastic disease*
V	F	80-7242	Neoplastic disease*
V	F	80-7253	Neoplastic disease
V	F	80-7257	Neoplastic disease*

Donovan E. Gordon, D.V.M., Ph.D.
Consultant Histopathologist
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of Veterinary Pathologists

PATHOLOGY APPENDIX C

LESION INCIDENCE COMPARISON
TABLE - MALES

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MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
BRAIN	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Leukemic infiltrates, lymphocytic	0/38	2/17	0/36	3/19	0/25	1/27	0/29	1/26	0/4	1/27
Leukemic infiltrates, monocytic	1/38	1/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	1/27
Hemorrhage	0/38	2/17	0/36	2/19	0/25	2/27	0/29	3/26	0/4	2/27
Bacteremia	0/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	1/27
Cerebrum, encephalomalacia	0/38	0/17	0/36	0/19	0/25	0/27	0/29	2/26	0/4	0/27
SPINAL CORD	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Leukemic infiltrates, lymphocytic	0/38	2/17	0/36	2/19	0/25	0/27	0/29	0/26	0/4	1/27
Leukemic infiltrates, monocytic	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	1/27
Myelomalacia	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27
Hemorrhage	0/38	1/17	0/36	2/19	0/25	0/27	0/29	1/26	0/4	0/27
PITUITARY	(37)	(16)	(36)	(18)	(24)	(27)	(29)	(26)	(4)	(27)
Adenoma	9/37	4/16	22/36	3/18	14/24	11/27	13/29	7/26	0/4	3/27
Carcinoma	2/37	1/16	1/36	0/18	0/24	2/27	2/29	1/26	0/4	0/27
Leukemic infiltrates, lymphocytic	1/37	2/16	0/36	4/18	0/24	2/27	1/29	3/26	0/4	1/27
Leukemic infiltrates, monocytic	2/37	2/16	0/36	2/18	0/24	2/27	0/29	7/26	0/4	4/27
Cyst	6/37	1/16	4/36	1/18	1/24	1/27	5/29	0/26	0/4	3/27
Hyperplasia, basophil-cell	0/37	0/16	0/36	1/18	0/24	1/27	1/29	1/26	0/4	2/27

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MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

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PITUITARY (continued)										
Hyperplasia, chromophobe-cell	8/37	3/16	2/36	3/18	3/24	0/27	1/29	2/26	0/4	3/27
Bacteremia	0/37	0/16	0/36	0/18	0/24	1/27	0/29	0/26	0/4	0/27
EYE	(37)	(17)	(2)	(1)	(1)	(3)	(2)	(3)	(4)	(27)
Keratitis, chronic	1/37	0/17	2/2	0/1	1/1	0/3	0/2	0/3	0/4	0/27
Keratitis with ulceration	0/37	0/17	0/2	0/1	0/1	0/3	0/2	1/3	0/4	0/27
Lens, cataract	7/37	2/17	0/2	1/1	1/1	1/3	2/2	1/3	2/4	3/27
Lens-induced inflammation	2/37	0/17	1/2	0/1	0/1	0/3	0/2	0/3	0/4	3/27
Degeneration, retinal	5/37	3/17	0/2	0/1	1/1	0/3	1/2	0/3	1/4	2/27
Retinal dysplasia	0/37	0/17	0/2	0/1	0/1	0/3	0/2	0/3	0/4	2/27
OPTIC NERVE	(37)	(17)	-	-	-	-	-	-	(4)	(27)
ADRENAL	(38)	(17)	(3)	(2)	(7)	(7)	(6)	(5)	(4)	(27)
Pheochromocytoma	10/38	7/17	2/3	2/2	4/7	2/7	3/6	3/5	1/4	3/27
Pheochromocytoma, malignant	0/38	0/17	0/3	0/2	3/7	1/7	2/6	0/5	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	3/17	0/3	0/2	0/7	0/7	1/6	1/5	0/4	0/27
Leukemic infiltrates, monocytic	9/38	3/17	0/3	0/2	1/7	0/7	1/6	1/5	2/4	3/27
Cortex, hyperplasia	1/38	0/17	0/3	0/2	0/7	0/7	0/6	0/5	0/4	0/27

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MALE F344 RATS

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ADRENAL (continued)										
Cortex, necrosis	1/38	0/17	0/3	0/2	0/7	0/7	0/6	0/5	0/4	0/27
Cortex, metamorphosis, fatty	15/38	9/17	0/3	0/2	0/7	0/7	0/6	0/5	2/4	4/27
Cortex, angiectasis	1/38	0/17	1/3	0/2	0/7	0/7	0/6	0/5	0/4	1/27
Medulla, hyperplasia	2/38	0/17	0/3	0/2	0/7	3/7	1/6	1/5	2/4	2/27
Extamedullary hematopoiesis	4/38	1/17	0/3	0/2	0/7	0/7	0/6	1/5	0/4	0/27
Angiectasis with fibrosis	1/38	0/17	0/3	0/2	0/7	0/7	0/6	0/5	0/4	0/27
SPLEEN	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Malignant lymphoma	0/38	6/17	1/36	6/19	2/25	4/27	1/29	4/26	0/4	1/27
Histiocytic sarcoma	0/38	0/17	1/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Monocytic leukemia	25/38	4/17	24/36	4/19	10/25	11/27	14/29	12/26	4/4	5/27
Hemangiosarcoma	0/38	1/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Congestion	3/38	0/17	2/36	0/19	4/25	0/27	3/29	2/26	0/4	0/27
Fibrosis	1/38	0/17	5/36	0/19	2/25	2/27	1/29	2/26	0/4	0/27
Increased extramedullary hematopoiesis	2/38	1/17	3/36	5/19	6/25	4/27	1/29	8/26	0/4	0/27
Increased pigment	0/38	3/17	0/36	1/19	7/25	4/27	11/29	4/26	0/4	18/27
Infarction	0/38	0/17	0/36	2/19	1/25	2/27	0/29	2/26	0/4	0/27
Osseous metaplasia	1/38	0/17	0/36	1/19	0/25	0/27	0/29	0/26	0/4	0/27
Accessory spleen	1/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27

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PANCREAS	(38)	(17)	(2)	(2)	(1)	(7)	(1)	(1)	(4)	(27)
Islet cell carcinoma	0/38	0/17	0/2	0/2	0/1	1/7	0/1	0/1	0/4	0/27
Islet cell adenoma	3/38	0/17	0/2	0/2	0/1	0/7	0/1	0/1	0/4	2/27
Acinar cell adenoma	1/38	0/17	0/2	0/2	0/1	0/7	0/1	0/1	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	4/17	0/2	1/2	0/1	0/7	0/1	0/1	0/4	0/27
Leukemic infiltrates, monocytic	4/38	2/17	0/2	0/2	0/1	0/7	0/1	1/1	0/4	1/27
Capsule, mesothelioma	0/38	0/17	1/2	0/2	0/1	0/7	0/1	0/1	0/4	0/27
Hyperplasia, islet cell	5/38	1/17	0/2	1/2	1/1	0/7	0/1	0/1	0/4	2/27
Atrophy, acinar cell	15/38	6/17	1/2	0/2	0/1	0/7	0/1	0/1	1/4	4/27
Lymphoid infiltrates, interstitial	2/38	0/17	0/2	0/2	0/1	0/7	0/1	0/1	0/4	0/27
Ductal ectasia	2/38	0/17	0/2	0/2	0/1	0/7	0/1	0/1	0/4	0/27
MESENTERIC LYMPH NODE	(38)	(17)	(2)	(4)	(1)	(5)	-	(6)	(4)	(26)
Monocytic leukemia	5/38	3/17	2/2	0/4	0/1	1/5	-	2/6	0/4	3/26
Malignant lymphoma	1/38	6/17	0/2	3/4	1/1	3/5	-	1/6	0/4	1/26
Lymphoid hyperplasia	0/38	1/17	0/2	0/4	0/1	0/5	-	0/6	0/4	0/26
Angiectasis	2/38	1/17	0/2	0/4	0/1	0/5	-	2/6	0/4	0/26
Extramedullary hematopoiesis	0/38	0/17	0/2	1/4	0/1	0/5	-	1/6	0/4	0/26

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TESTIS	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Capsule/NOS, mesothelioma	0/38	0/16	2/36	0/19	0/25	0/27	0/29	0/26	0/4	3/27
Interstitial cell tumor	35/38	12/16	34/36	15/19	24/25	23/27	27/29	24/26	4/4	12/27
Hyperplasia, interstitial cell	5/38	2/16	3/36	3/19	2/25	9/27	1/29	1/26	0/4	2/27
Hypospermatogenesis	0/38	0/16	1/36	2/19	0/25	4/27	0/29	2/26	0/4	0/27
Germinal cell degeneration	4/38	1/16	9/36	7/19	4/25	10/27	7/29	6/26	1/4	3/27
Tubules, atrophy, compression	34/38	12/16	33/36	12/19	20/25	15/27	26/29	22/26	4/4	6/27
Arteritis, chronic	0/38	0/16	0/36	0/19	1/25	1/27	1/29	0/26	0/4	0/27
PROSTATE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Adenoma	1/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Leukemic infiltrates, lymphocytic	0/38	0/16	0/36	1/19	0/25	1/27	0/29	1/26	0/4	0/27
Leukemic infiltrates, monocytic	0/38	1/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Hyperplasia, adenomatous	0/38	1/16	1/36	0/19	0/25	2/27	0/29	0/26	1/4	0/27
Inflammation, subacute	1/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Inflammation, chronic-active	15/38	5/16	13/36	5/19	6/25	7/27	6/29	5/26	1/4	1/27
Inflammation, suppurative	0/38	2/16	1/36	3/19	2/25	7/27	4/29	8/26	0/4	19/27
Microabscesses	0/38	0/16	0/36	1/19	0/25	1/27	0/29	0/26	0/4	1/27
Cysts	0/38	0/16	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27

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EPIDIDYMIS	(38)	(17)	(36)	(19)	(25)	(26)	(29)	(26)	(4)	(27)
Capsule, mesothelioma	0/38	0/17	2/36	0/19	0/25	0/26	0/29	0/26	0/4	1/27
Leukemic infiltrates, monocytic	0/38	0/17	0/36	0/19	0/25	1/26	0/29	1/26	0/4	0/27
Spermatic granuloma(s)	0/38	1/17	1/36	1/19	1/25	0/26	0/29	0/26	1/4	1/27
Diminution of sperm in ducts	1/38	4/17	8/36	6/19	0/25	7/26	3/29	3/26	1/4	4/27
Absence of sperm in ducts	34/38	11/17	27/36	12/19	23/25	16/26	26/29	22/26	3/4	5/27
Cellular debris in ducts	30/38	9/17	26/36	10/19	13/25	13/26	23/29	12/26	2/4	9/27
SEMINAL VESICLE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Leukemic infiltrates, lymphocytic	0/38	1/16	0/36	2/19	0/25	0/27	0/29	0/26	0/4	0/27
Leukemic infiltrates, monocytic	2/38	1/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Inflammation, chronic-active	0/38	0/16	0/36	0/19	0/25	1/27	1/29	0/26	0/4	0/27
Inflammation, suppurative	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	8/27
Distended with secretion	0/38	0/16	0/36	1/19	0/25	0/27	0/29	0/26	1/4	18/27
URINARY BLADDER	(38)	(16)	-	(6)	-	(3)	(2)	(4)	(4)	(27)
Transitional cell carcinoma	1/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	0/27
Leukemic infiltrates, lymphocytic	0/38	1/16	-	1/6	-	0/3	0/2	0/4	0/4	1/27
Leukemic infiltrates, monocytic	3/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	2/27
Cystitis, suppurative	0/38	0/16	-	0/6	-	0/3	1/2	0/4	0/4	0/27

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URINARY BLADDER (continued)										
Cystitis, hemorrhagic-suppurative	0/38	0/16	-	2/6	-	1/3	0/2	0/4	0/4	17/27
Cystitis, hemorrhagic	0/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	1/27
Lymphoid aggregates, submucosal	1/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	0/27
Mineralization, uremic	0/38	0/16	-	0/6	-	0/3	0/2	0/4	0/4	1/27
Distention, luminal	0/38	0/16	-	2/6	-	1/3	0/2	3/4	1/4	23/27
LUNG-MAINSTEM BRONCHI	(38)	(17)	(5)	(10)	(4)	(13)	(5)	(11)	(4)	(27)
Alveolar adenoma	1/38	0/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	0/27
Bronchiolar-alveolar adenoma	1/38	0/17	0/5	0/10	1/4	0/13	0/5	0/11	0/4	1/27
Hemangiosarcoma	0/38	0/17	0/5	0/10	0/4	1/13	0/5	0/11	0/4	0/27
Carcinoma, metastatic, adrenal	0/38	0/17	0/5	0/10	2/4	0/13	1/5	1/11	0/4	0/27
Carcinoma, metastatic, NOS	0/38	0/17	0/5	0/10	0/4	1/13	0/5	0/11	0/4	0/27
Sarcoma, metastatic	0/38	0/17	0/5	0/10	0/4	0/13	1/5	0/11	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	6/17	0/5	5/10	1/4	1/13	0/5	3/11	0/4	1/27
Leukemic infiltrates, monocytic	12/38	4/17	3/5	1/10	1/4	3/13	4/5	6/11	2/4	5/27
Adenomatosis	0/38	1/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	0/27
Microabscesses	0/38	0/17	0/5	0/10	0/4	1/13	0/5	0/11	0/4	0/27
Inflammation, granulomatous	0/38	0/17	0/5	0/10	0/4	1/13	0/5	0/11	0/4	0/27
Alveolar macrophages	3/38	1/17	2/5	1/10	0/4	0/13	0/5	1/11	1/4	6/27

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LUNG-MAINSTEM BRONCHI (continued)										
Lymphoid infiltrates,										
peribronchial/iolar	37/38	17/17	2/5	0/10	0/4	0/13	0/5	0/11	4/4	26/27
Hemorrhage	1/38	0/17	1/5	0/10	0/4	0/13	0/5	0/11	0/4	2/27
Congestion, agonal	0/38	0/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	5/27
Mineralization, alveolar	0/38	0/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	1/27
Osseous metaplasia	2/38	0/17	0/5	0/10	0/4	0/13	0/5	0/11	0/4	0/27
Fibrinoid degeneration, septae	0/38	0/17	0/5	0/10	1/4	0/13	0/5	1/11	0/4	0/27
ESOPHAGUS	(38)	(17)	-	(1)	-	(2)	-	-	(4)	(27)
TRACHEA	(38)	(17)	-	(1)	-	(2)	-	-	(4)	(27)
Leukemic infiltrates, monocytic	0/38	0/17	-	0/1	-	0/2	-	-	0/4	1/27
Inflammation, chronic	9/38	1/17	-	0/1	-	0/2	-	-	4/4	5/27
Mucocele(s), submucosal	3/38	0/17	-	0/1	-	0/2	-	-	0/4	0/27
THYROID	(38)	(17)	(1)	-	(2)	(3)	(2)	-	(4)	(27)
C-cell adenoma	4/38	4/17	0/1	-	0/2	0/3	1/2	-	1/4	2/27
Follicular carcinoma	0/38	0/17	0/1	-	0/2	1/3	0/2	-	0/4	0/27
Follicular adenoma	0/38	0/17	0/1	-	0/2	1/3	0/2	-	0/4	0/27

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LESION INCIDENCE COMPARISON TABLE

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TYYROID (continued)										
Follicular cystadenocarcinoma	0/38	0/17	0/1	-	0/2	0/3	1/2	-	0/4	0/27
Follicular cystadenoma	3/38	0/17	0/1	-	0/2	0/3	0/2	-	0/4	1/27
Leukemic infiltrates, lymphocytic	0/38	1/17	0/1	-	0/2	0/3	0/2	-	0/4	0/27
Hyperplasia, C-cell	7/38	1/17	1/1	-	1/2	0/3	0/2	-	0/4	0/27
Cystic follicle(s)	11/38	1/17	0/1	-	0/2	0/3	0/2	-	1/4	4/27
PARATHYROID	(37)	(17)	-	-	-	-	-	-	(4)	(27)
Adenoma	1/37	0/17	-	-	-	-	-	-	0/4	0/27
Hyperplasia	2/37	0/17	-	-	-	-	-	-	1/4	11/27
HEART	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Endocardial neurolemmoma	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	3/17	0/36	3/19	0/25	1/27	0/29	3/26	0/4	1/27
Leukemic infiltrates, monocytic	5/38	1/17	1/36	1/19	0/25	2/27	0/29	4/26	1/4	2/27
Myocarditis, chronic	37/38	12/17	27/36	9/19	25/25	18/27	27/29	18/26	4/4	22/27
Auricular thrombosis	1/38	1/17	0/36	1/19	1/25	2/27	0/29	2/26	0/4	2/27
Mineralization, vessels, uremic	0/38	0/17	0/36	1/19	0/25	1/27	0/29	0/26	0/4	6/27
Mineralization, myocardial, uremic	0/38	0/17	0/36	1/19	0/25	1/27	0/29	0/26	0/4	2/27

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HEART (continued)										
Vegetative endocarditis	0/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	1/27
Bacteremia	0/38	0/17	0/36	0/19	0/25	1/27	0/29	0/26	0/4	1/27
LIVER	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Neoplastic nodule	3/38	1/17	3/36	0/19	0/25	0/27	1/29	1/26	1/4	0/27
Hepatocellular carcinoma	0/38	1/17	0/36	0/19	0/25	0/27	1/29	1/26	0/4	2/27
Hemangioma	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27
Histiocytic sarcoma	0/38	0/17	0/36	0/19	0/25	1/27	0/29	1/26	0/4	0/27
Malignant fibrous histiocytoma	0/38	0/17	1/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	5/17	1/36	5/19	3/25	4/27	1/29	3/26	0/4	1/27
Leukemic infiltrates, monocytic	24/38	4/17	25/36	4/19	10/25	10/27	14/29	12/26	3/4	5/27
Focus/foci of hyperplasia with cystic degeneration	5/38	0/17	3/36	0/19	2/25	0/27	1/29	2/26	0/4	0/27
Area(s) of hyperplasia with cystic degeneration	10/38	0/17	9/36	1/19	4/25	1/27	10/29	0/26	1/4	1/27
Foci of cellular alteration-basophilic	29/38	2/17	29/36	3/19	20/25	8/27	25/29	7/26	3/4	1/27
Foci of cellular alteration-eosinophilic	6/38	0/17	18/36	1/19	10/25	1/27	8/29	0/26	3/4	0/27
Foci of cellular alteration-clear cells	0/38	0/17	0/36	0/19	0/25	0/27	1/29	0/26	0/4	0/27
Area of cellular alteration-clear cells	1/38	0/17	1/36	0/19	0/25	1/27	4/29	0/26	0/4	0/27

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LIVER (continued)										
Foci of cellular alteration-mixed cells	14/38	0/17	4/36	0/19	4/25	0/27	7/29	0/26	0/4	2/27
Necrosis, random	2/38	0/17	1/36	1/19	1/25	0/27	0/29	1/26	1/4	0/27
Necrosis, liquefaction	0/38	1/17	0/36	1/19	0/25	0/27	1/29	0/26	0/4	1/27
Necrosis, centrilobular, agonal	0/38	2/17	0/36	5/19	0/25	6/27	0/29	6/26	0/4	2/27
Bile duct proliferation	38/38	14/17	36/36	18/19	24/25	26/27	28/29	26/26	4/4	15/27
Cholangiofibrosis	27/38	8/17	26/36	11/19	13/25	14/27	22/29	15/26	2/4	8/27
Metamorphosis, fatty	0/38	3/17	3/36	6/19	0/25	8/27	1/29	2/26	0/4	0/27
Mononuclear cell infiltrates,										
sinusoidal	1/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Extramedullary hematopoiesis	1/38	0/17	0/36	0/19	2/25	3/27	0/29	1/26	0/4	0/27
Cyst, parenchymal	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27
Hematocyst	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27
Microgranulomas	0/38	0/17	0/36	0/19	0/25	1/27	0/29	1/26	0/4	0/27
Bacteremia	0/38	0/17	0/36	0/19	0/25	1/27	0/29	0/26	0/4	0/27
KIDNEY	(38)	(17)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Tubular adenoma	0/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	1/27
Hemangioma	0/38	0/17	0/36	1/19	0/25	0/27	0/29	0/26	0/4	0/27
Leukemic infiltrates, lymphocytic	1/38	5/17	0/36	5/19	0/25	3/27	1/29	1/26	0/4	1/27

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KIDNEY (continued)										
Leukemic infiltrates, monocytic	3/38	1/17	0/36	1/19	0/25	3/27	1/29	4/26	0/4	2/27
Nephropathy, chronic	38/38	17/17	36/36	19/19	25/25	27/27	29/29	26/26	4/4	26/27
Inflammation, lymphocytic	38/38	11/17	36/36	8/19	22/25	14/27	29/29	16/26	4/4	6/27
Microconcretions, tubular	0/38	0/17	0/36	0/19	0/25	0/27	0/29	1/26	1/4	1/27
Pyelonephritis	0/38	0/17	0/36	0/19	0/25	2/27	1/29	1/26	0/4	1/27
Pyelitis, suppurative	0/38	0/17	0/36	1/19	0/25	0/27	0/29	1/26	0/4	5/27
Cortex, increased pigment	2/38	7/17	4/36	2/19	2/25	2/27	0/29	4/26	0/4	0/27
Cortex, protein resorption droplets	0/38	1/17	3/36	1/19	4/25	1/27	2/29	3/26	0/4	1/27
Necrosis, medullary papilla	0/38	0/17	0/36	1/19	0/25	0/27	0/29	0/26	0/4	18/27
Mineralization, uremic	1/38	0/17	0/36	1/19	0/25	2/27	0/29	0/26	0/4	13/27
Cyst, cortical	1/38	0/17	1/36	0/19	0/25	1/27	2/29	0/26	0/4	0/27
Infarction	0/38	0/17	0/36	0/19	0/25	0/27	0/29	0/26	0/4	1/27
Bacteremia	0/38	0/17	0/36	0/19	0/25	1/27	0/29	0/26	0/4	1/27
STOMACH	(38)	(17)	-	(1)	(1)	(4)	-	(6)	(4)	(27)
Leukemic infiltrates, lymphocytic	0/38	2/17	-	0/1	0/1	0/4	-	0/6	0/4	0/27
Leukemic infiltrates, monocytic	1/38	1/17	-	0/1	0/1	0/4	-	0/6	0/4	2/27
Mucosal ulcer(s), forestomach	0/38	1/17	-	0/1	0/1	0/4	-	0/6	0/4	0/27
Microgranuloma, forestomach	0/38	1/17	-	0/1	0/1	0/4	-	0/6	0/4	0/27

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STOMACH (continued)										
Mucosal ulcer(s), glandular region	0/38	2/17	-	0/1	0/1	0/4	-	3/6	0/4	0/27
Mucosal erosion(s), glandular region	0/38	1/17	-	0/1	0/1	1/4	-	4/6	0/4	2/27
Mineralization, uremic	1/38	0/17	-	0/1	0/1	0/4	-	0/6	0/4	12/27
Bacteremia	0/38	0/17	-	0/1	0/1	0/4	-	0/6	0/4	1/27
DUODENUM	(38)	(16)	(1)	-	(1)	(3)	-	-	(4)	(26)
Leukemic infiltrates, lymphocytic	0/38	1/16	0/1	-	0/1	0/3	-	-	0/4	0/26
Mucosal ulcers	0/38	0/16	1/1	-	0/1	0/3	-	-	0/4	0/26
JEJUNUM	(38)	(15)	-	-	(1)	(3)	-	-	(4)	(25)
ILEUM	(38)	(15)	-	-	(1)	(3)	-	-	(4)	(23)
Leukemic infiltrates, lymphocytic	0/38	1/15	-	-	0/1	0/3	-	-	0/4	0/23
CECUM	(38)	(16)	-	(1)	(1)	(4)	-	-	(4)	(27)
Nematode parasites in lumen	4/38	2/16	-	0/1	0/1	0/4	-	-	0/4	2/27
Inflammation with ulceration	0/38	1/16	-	0/1	0/1	0/4	-	-	0/4	0/27
Inflammation	0/38	0/16	-	0/1	1/1	1/4	-	-	0/4	0/27
Mineralization, uremic	1/38	0/16	-	0/1	0/1	0/4	-	-	0/4	0/27

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CECUM (continued)										
Bacteremia	0/38	0/16	-	0/1	0/1	0/4	-	-	0/4	1/27
COLON	(38)	(16)	-	-	-	(3)	-	-	(4)	(27)
Leukemic infiltrates, monocytic	1/38	0/16	-	-	-	0/3	-	-	0/4	0/27
Nematode parasites in lumen	11/38	2/16	-	-	-	0/3	-	-	2/4	3/27
RECTUM	(38)	(16)	-	-	-	(2)	-	(2)	(4)	(27)
Nematode parasites in lumen	3/38	0/16	-	-	-	0/2	-	0/2	1/4	1/27
SKIN	(38)	(17)	(11)	(6)	(6)	(8)	(5)	(11)	(4)	(27)
Malignant fibrous histiocytoma	0/38	0/17	0/11	0/6	1/6	0/8	0/5	0/11	0/4	0/27
Dermal fibrosarcoma	0/38	0/17	1/11	0/6	0/6	0/8	0/5	1/11	0/4	0/27
Dermal fibroma	3/38	0/17	2/11	2/6	3/6	2/8	2/5	3/11	0/4	0/27
Basal cell tumor, benign	0/38	0/17	0/11	1/6	0/6	0/8	0/5	0/11	0/4	0/27
Dermal hemangioma	0/38	0/17	0/11	0/6	0/6	0/8	0/5	1/11	0/4	0/27
Keratoacanthoma	1/38	0/17	3/11	0/6	0/6	0/8	0/5	2/11	0/4	0/27
Papilloma	1/38	1/17	2/11	0/6	0/6	1/8	0/5	0/11	0/4	0/27
Leukemic infiltrates, lymphocytic	0/38	4/17	0/11	0/6	0/6	0/8	0/5	0/11	0/4	0/27
Leukemic infiltrates, monocytic	1/38	1/17	0/11	0/6	0/6	0/8	0/5	0/11	0/4	1/27

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SKIN (continued)										
Epidermal inclusion cyst	0/38	0/17	2/11	0/6	0/6	0/8	2/5	3/11	1/4	0/27
Epidermal ulceration	0/38	0/17	0/11	0/6	1/6	0/8	0/5	1/11	0/4	1/27
Inflammation, chronic	1/38	0/17	0/11	0/6	0/6	0/8	0/5	0/11	0/4	0/27
Inflammation, dermal	0/38	0/17	0/11	0/6	1/6	0/8	0/5	0/11	1/4	2/27
Acanthosis	0/38	0/17	1/11	0/6	0/6	0/8	1/5	0/11	0/4	0/27
Exudative crusts	0/38	0/17	1/11	0/6	0/6	0/8	0/5	0/11	1/4	1/27
MAMMARY GLAND	(37)	(16)	(3)	-	(3)	(4)	(2)	(1)	(4)	(20)
Fibroadenoma	2/37	0/16	1/3	-	2/3	2/4	1/2	0/1	0/4	0/20
Galactoceles	6/37	3/16	2/3	-	1/3	1/4	1/2	1/1	0/4	1/20
Inflammation	0/37	0/16	0/3	-	0/3	0/4	1/2	0/1	0/4	0/20
STERNUM	(38)	(17)	-	(1)	-	(1)	-	-	(4)	(27)
BONE MARROW	(38)	(16)	-	(1)	-	(1)	-	(2)	(4)	(27)
Leukemic infiltrates, lymphocytic	0/38	3/16	-	1/1	-	0/1	-	0/2	0/4	0/27
Leukemic infiltrates, monocytic	1/38	1/16	-	0/1	-	1/1	-	2/2	0/4	0/27
Myelofibrosis	1/38	0/16	-	0/1	-	0/1	-	0/2	0/4	0/27
Hypocellular	1/38	0/16	-	0/1	-	0/1	-	0/2	0/4	0/27

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TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP										
HARDERIAN GLAND	(1)	-	-	-	-	-	-	-	-	
Dacryoadenitis, unilateral	1/1	-	-	-	-	-	-	-	-	
ZYMBAL'S GLAND	(1)	-	-	-	-	(1)	-	-	-	-
Carcinoma	1/1	-	-	-	-	1/1	-	-	-	-
MESENTERY/ABDOMINAL CAVITY	(10)	(4)	(4)	(3)	(4)	(9)	(8)	(10)	(1)	(6)
Mesothelioma, malignant/NOS										
(multiple sites)	0/10	1/4	2/4	0/3	0/4	2/9	0/8	1/10	0/1	0/6
Fibrous histiocytoma (multiple										
sites)	0/10	0/4	0/4	0/3	1/4	1/9	0/8	1/10	0/1	0/6
Leukemic infiltrates, lymphocytic	0/10	1/4	0/4	0/3	0/4	1/9	0/8	1/10	0/1	0/6
Leukemic infiltrates, monocytic	0/10	0/4	0/4	0/3	0/4	0/9	0/8	1/10	0/1	0/6
Inflammation (peritonitis)	0/10	0/4	0/4	0/3	0/4	0/9	0/8	0/10	0/1	1/6
Lipogranuloma/fat necrosis	10/10	3/4	2/4	2/3	3/4	6/9	8/8	8/10	1/1	5/6
Arteritis, chronic	0/10	0/4	0/4	0/3	1/4	0/9	0/8	0/10	0/1	0/6
Microabscesses	0/10	0/4	0/4	0/3	0/4	1/9	0/8	0/10	0/1	0/6
COAGULATING GLAND	(1)	-	-	(3)	-	(2)	-	(2)	(1)	(2)
Spermatic granuloma(s)	1/1	-	-	3/3	-	2/2	-	2/2	1/1	1/2
Inflammatory exudate in ducts	0/1	-	-	0/3	-	0/2	-	0/2	0/1	1/2

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MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP (continued)										
PREPUTIAL GLAND	(4)	(1)	(4)	(1)	(2)	(2)	(5)	(3)	-	(1)
Carcinoma	2/4	0/1	1/4	1/1	0/2	1/2	0/5	0/3	-	0/1
Adenoma	1/4	1/1	1/4	0/1	1/2	0/2	4/5	1/3	-	0/1
Inflammation	0/4	0/1	2/4	0/1	1/2	0/2	0/5	1/3	-	0/1
Abscess	1/4	0/1	0/4	0/1	0/2	0/2	0/5	1/3	-	0/1
Cysts	0/4	0/1	1/4	0/1	0/2	0/2	1/5	0/3	-	0/1
Inflammatory exudate	0/4	0/1	0/4	0/1	0/2	1/2	0/5	0/3	-	0/1
THYMUS	(1)	(5)	-	(5)	(1)	(4)	-	(3)	-	(3)
Monocytic leukemia	1/1	2/5	-	0/5	0/1	1/4	-	0/3	-	0/3
Malignant lymphoma	0/1	3/5	-	3/5	0/1	0/4	-	2/3	-	1/3
Lymphoid hyperplasia	0/1	0/5	-	1/5	0/1	0/4	-	0/3	-	0/3
Atrophy	0/1	0/5	-	0/5	0/1	2/4	-	1/3	-	1/3
Atrophy with cysts	0/1	0/5	-	1/5	0/1	0/4	-	0/3	-	1/3
Angiectasis	0/1	0/5	-	0/5	0/1	1/4	-	0/3	-	0/3
LYMPH NODE(S), NOS	(5)	(7)	(2)	(7)	(3)	(11)	(4)	(8)	-	(5)
Monocytic leukemia	4/5	1/7	1/2	2/7	1/3	3/11	1/4	3/8	-	1/5
Malignant lymphoma	0/5	5/7	1/2	5/7	2/3	4/11	1/4	3/8	-	2/5
Carcinoma, metastatic, adrenal	0/5	0/7	0/2	0/7	0/3	0/11	0/4	1/8	-	0/5

Code: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

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MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP (continued)										
LYMPH NODE(S), NOS (continued)										
Lymphoid hyperplasia	0/5	0/7	0/2	0/7	0/3	1/11	2/4	0/8	-	1/5
Hyperlasia, lymphoid and plasma cell	1/5	0/7	0/2	0/7	0/3	0/11	0/4	0/8	-	0/5
Angiectasis	0/5	1/7	0/2	0/7	0/3	2/11	0/4	2/8	-	0/5
SUBCUTIS	-	-	(1)	(1)	-	-	-	-	-	-
Lipoma	-	-	1/1	0/1	-	-	-	-	-	-
Liposarcoma	-	-	0/1	1/1	-	-	-	-	-	-
NASAL TISSUE	-	-	-	-	-	-	-	-	-	(1)
Inflammatory exudate	-	-	-	-	-	-	-	-	-	1/1
SALIVARY GLAND	-	-	-	(1)	-	(2)	-	(1)	-	-
Histiocytic sarcoma	-	-	-	0/1	-	0/2	-	1/1	-	-
PROSTATIC URETHRAL GLAND	-	-	-	-	-	-	-	(1)	-	-
Hemangioma	-	-	-	-	-	-	-	1/1	-	-
URETER	-	-	-	(1)	-	-	-	-	-	-
Dilatation	-	-	-	1/1	-	-	-	-	-	-
Peritonitis	-	-	-	1/1	-	-	-	-	-	-
FEMUR/BONE	-	-	-	(1)	-	(2)	-	(2)	-	-

de: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

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MALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence RDX 0.0 mg/kg/day	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence RDX 0.3 mg/kg/day	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence RDX 1.5 mg/kg/day	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence RDX 8.0 mg/kg/day	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence RDX 40.0 mg/kg/day
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP (continued)										
PENIS	-	(1)	-	-	-	-	-	-	-	(2)
LARYNX	-	-	-	-	-	(1)	-	-	-	-
MUSCLE, NOS	-	-	-	-	-	(1)	-	-	-	-

Code: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

PATHOLOGY APPENDIX D

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE - MALES

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F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
BRAIN	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic						P														
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	N	N	L	L	L	L	L	L	L	N	L	N	L	L	N	L	L
Adenoma	P	P						P						P		P			P	
Carcinoma						P				P										
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic						P														
Cyst			P						P								P			
Hyperplasia, chromophobe-cell							2		2		1	1					1			2
EYE	NN	MM	NN	NN	NL	LL	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Keratitis, chronic, unilateral/																				
bilateral, focal																				

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				P
Hemorrhage, focal																				3
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
PITUITARY	L	N	N	N	L	L	N	N	N	N	L	L	N	M	L	N	L	L	L	L
Adenoma											P	P					P			
Carcinoma																				
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic					P															P
Cyst	P				P	P														
Hyperplasia, chromophobe-cell					1										1				2	
EYE	NL	NN	NN	NN	NN	NL	NN	NN	NM	NN	NN	NN	NL	NN	NL	NL	LL	NN	NN	NL
Keratitis, chronic, unilateral/ bilateral, focal	1																			

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
BRAIN	N	L	N	N	N	N	N	N	N	L	N	N	N	N	N							
Leukemic infiltrates, lymphocytic		P								P											0/38	2/17
Leukemic infiltrates, monocytic																					1/38	1/17
Hemorrhage, focal										3											0/38	2/17
SPINAL CORD	N	L	N	N	N	N	N	N	N	L	N	N	N	N	N							
Leukemic infiltrates, lymphocytic		P								P											0/38	2/17
Hemorrhage, focal										2											0/38	1/17
PITUITARY	N	L	L	N	L	L	N	L	L	M	N	L	L	L	N							
Adenoma		P	P		P							P									9/37	4/16
Carcinoma						P															2/37	1/16
Leukemic infiltrates, lymphocytic		P												P							1/37	2/16
Leukemic infiltrates, monocytic								P													2/37	2/16
Cyst								P													6/37	1/16
Hyperplasia, chromophobe-cell									1				2								8/37	3/16
EYE	NN	NN	NN	NN	NN	LL	NN	NN	NN	NN	NN	NN	NN	NN	NL							
Keratitis, chronic, unilateral/																						
bilateral, focal																					1/37	0/17

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
EYE (continued)																				
Lens, cataract, unilateral/bilateral					P	P														
Lens-induced inflammation, unilateral							P													
Degeneration, retinal, unilateral/																				
bilateral					3	2														
OPTIC NERVE	NN	MM	NN	NN	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
ADRENAL	LL	LL	NL	NL	NL	LL	LL	NN	NL	LL	NN	LL	LL	LL	LL	LL	LL	LL	LL	NN
Pheochromocytoma, unilateral/bilateral				P						P		P	P	P	P	P				
Leukemic inflitrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral	P	P				P			P						P		P			
Cortex, hyperplasia, unilateral/																				
bilateral																				
Cortex, necrosis, unilateral/bilateral,																				
focal																				
Cortex, metamorphosis, fatty, unilateral/																				
bilateral	2	1	1		1	1			1			2	1	2				1	1	

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
EYE (continued)																				
Lens, cataract, unilateral/bilateral						P							P		P	P	P			P
Lens-induced inflammation, unilateral													P							
Degeneration, retinal, unilateral/																				
bilateral													3			3	3			3
OPTIC NERVE	NN	NN	NN	NN	NN	NN	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
ADRENAL	NN	NN	LL	NL	LL	NL	LL	LL	NN	NL	NL	LL	NN	NL	NL	NL	NN	LM	LL	LL
Pheochromocytoma, unilateral/bilateral								P			P					P			P	
Leukemic inflitrates, lymphocytic,																				
unilateral/bilateral																		P		
Leukemic infiltrates, monocytic,																				
unilateral/bilateral			P		P									P						P
Cortex, hyperplasia, unilateral/																				
bilateral								3												
Cortex, necrosis, unilateral/bilateral,																				
focal								3												
Cortex, metamorphosis, fatty, unilateral/																				
bilateral				3		1				1		1								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] = terminal sac[illegible] [illegible]OMS [illegible]ontaneous death/moribund sacrifice

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F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
EYE (continued)																						
Lens, cataract, unilateral/bilateral															P						7/37	2/17
Lens-induced inflammation, unilateral																					2/37	0/17
Degeneration, retinal, unilateral/																						
bilateral						3									3						5/37	3/17
OPTIC NERVE	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN							
ADRENAL	LL	LL	NN	NL	NL	NN	LL	LL	LL	LL	LL	NL	LL	LL	LL							
Pheochromocytoma, unilateral/bilateral	P			P				P	P	P			P								10/38	7/17
Leukemic inflitrates, lymphocytic,																						
unilateral/bilateral		P								P				P							1/38	3/17
Leukemic infiltrates, monocytic,																						
unilateral/bilateral								P	P												9/38	3/17
Cortex, hyperplasia, unilateral/																						
bilateral																					1/38	0/17
Cortex, necrosis, unilateral/bilateral,																						
focal																					1/38	0/17
Cortex, metamorphosis, fatty, unilateral/																						
bilateral					1		1	1	3	3		1	2	3	2						15/38	9/17

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
ADRENAL (continued)																				
Cortex, angiectasis, unilateral/																				
bilateral, focal							3													
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral																				
Extamedullary hematopoiesis, focal/																				
multifocal, unilateral/bilateral							1					1						1		
Angiectasis with fibrosis																				
SPLEEN	L	L	N	L	L	L	L	L	L	L	N	L	L	N	L	L	L	L	L	L
Malignant lymphoma																				
Monocytic leukemia	P	P			P	P	P	P	P	P		P	P		P		P		P	P
Hemangiosarcoma																				
Congestion, diffuse																2		2		
Fibrosis, focal																				
Increased extramedullary hematopoiesis				1																
Increased pigment, diffuse																				
Accessory spleen																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
ADRENAL (continued)																				
Cortex, angiectasis, unilateral/																				
bilateral, focal																				
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral							2					2								
Extamedullary hematopoiesis, focal/																				
multifocal, unilateral/bilateral						1														
Angiectasis with fibrosis															P					
SPLEEN	N	L	L	L	L	N	L	N	L	L	L	L	L	L	L	L	L	L	N	L
Malignant lymphoma																				
Monocytic leukemia			P		P		P			P	P	P	P	P	P	P	P			P
Hemangiosarcoma																				
Congestion, diffuse		2																		
Fibrosis, focal				3																
Increased extramedullary hematopoiesis									3											
Increased pigment, diffuse																				
Accessory spleen												P								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice

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RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
ADRENAL (continued)																						
Cortex, angiectasis, unilateral/																						
bilateral, focal																					1/38	0/17
Medulla, hyperplasia, focal/multifocal,																						
unilateral/bilateral																					2/38	0/17
Extamedullary hematopoiesis, focal/																						
multifocal, unilateral/bilateral											1										4/38	1/17
Angiectasis with fibrosis																					1/38	0/17
SPLEEN	L	L	L	N	L	N	L	L	L	L	L	L	L	L	L							
Malignant lymphoma		P							P	P			P	P	P						0/38	6/17
Monocytic leukemia	P						P	P													25/38	4/17
Hemangiosarcoma										P											0/38	1/17
Congestion, diffuse																					3/38	0/17
Fibrosis, focal																					1/38	0/17
Increased extramedullary hematopoiesis											3										2/38	1/17
Increased pigment, diffuse			2		2							3									0/38	3/17
Accessory spleen																					1/38	0/17

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
PANCREAS	L	L	N	N	L	L	L	L	L	L	N	N	L	L	N	N	N	N	N	N
Islet cell adenoma										P			P	P						
Acinar cell adenoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P	P				P														
Hyperplasia, islet cell, focal																				
Atrophy, acinar cell, focal/multifocal	2				3		3	3	3				2							
Lymphoid infiltrates, interstitial									1				2							
Ductal ectasia, focal													2							
MESENTERIC LYMPH NODE	L	L	N	N	N	L	L	N	N	N	N	N	N	N	N	N	N	L	N	N
Monocytic leukemia	P	P				P	P													
Malignant lymphoma																				
Lymphoid hyperplasia																				
Angiectasis, focal/multifocal																		2		
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	NL	LL
Interstitial cell tumor, unilateral/ bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P		P

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present [illegible] = tissue section inadequate ** = moribund sacrifice
[illegible] = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
PANCREAS	L	N	L	L	L	L	N	N	L	L	N	L	L	L	L	N	L	L	N	N
Islet cell adenoma																				
Acinar cell adenoma				P																
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic					P															
Hyperplasia, islet cell, focal				2		2			2					2				2		
Atrophy, acinar cell, focal/multifocal	1		3	3	3					2		3	2		3		2			
Lymphoid infiltrates, interstitial																				
Ductal ectasia, focal														2						
MESENTERIC LYMPH NODE	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	L	L	L	N
Monocytic leukemia					P															
Malignant lymphoma																		P		
Lymphoid hyperplasia																				
Angiectasis, focal/multifocal																	2		3	
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NL	LL	LL	LL	LL
Interstitial cell tumor, unilateral/ bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
T = terminal sacrifice CPMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
PANCREAS	L	L	L	N	L	N	N	L	N	L	L	L	L	L	N							
Islet cell adenoma																					3/38	0/17
Acinar cell adenoma																					1/38	0/17
Leukemic infiltrates, lymphocytic		P								P			P	P							1/38	4/17
Leukemic infiltrates, monocytic	P							P													4/38	2/17
Hyperplasia, islet cell, focal					2																5/38	1/17
Atrophy, acinar cell, focal/multifocal		3	2							2	2	1		2							15/38	6/17
Lymphoid infiltrates, interstitial																					2/38	0/17
Ductal ectasia, focal																					2/38	0/17
MESENTERIC LYMPH NODE	L	L	N	N	N	N	L	L	L	L	L	N	L	L	L							
Monocytic leukemia	P						P	P													5/38	3/17
Malignant lymphoma		P							P	P			P	P	P						1/38	6/17
Lymphoid hyperplasia											2										0/38	1/17
Angiectasis, focal/multifocal																					2/38	1/17
TESTIS	LL	LL	LL	NN	NN	LL	LL	LL	LL	LL	MM	NL	LL	LL	LL							
Interstitial cell tumor, unilateral/ bilateral	P	P	P			P	P	P	P	P			P		P						35/38	12/16

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
TESTIS (continued)																				
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral		1				2				3									2	
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral		3				3														
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3		3	3	3	3	3	3	3	3	3	3	3		3	3	3	3		3
PROSTATE	L	N	N	N	N	N	N	N	L	L	N	N	N	L	N	N	L	N	N	L
Adenoma																				
Leukemic infiltrates, monocytic																				
Hyperplasia, adenomatous, focal																				
Inflammation, subacute, focal										1										
Inflammation, chronic-active	2								2					2			1			2
Inflammation, suppurative																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
TESTIS (continued)																				
Hyperplasia, interstitial cell, focal, unilateral/bilateral																2				
Germinal cell degeneration, focal/ multifocal/diffuse, unilateral/ bilateral					3												3			
Tubules, atrophy, compression, focal/multifocal/diffuse, unilateral/bilateral	3	3	3	3	3	3	3	3	3	3	3	3	2	3	2		3	3	3	3
PROSTATE	L	L	L	N	L	L	N	L	N	N	N	L	N	L	L	N	L	N	N	N
Adenoma		P																		
Leukemic infiltrates, monocytic																				
Hyperplasia, adenomatous, focal																				
Inflammation, subacute, focal																				
Inflammation, chronic-active	1	1	1		1	1		2				1		1	2		2			
Inflammation, suppurative																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
TESTIS (continued)																						
Hyperplasia, interstitial cell, focal,																						
unilateral/bilateral												2		2							5/38	2/16
Germinal cell degeneration, focal/																						
multifocal/diffuse, unilateral/																						
bilateral													3								4/38	1/16
Tubules, atrophy, compression,																						
focal/multifocal/diffuse,																						
unilateral/bilateral	2	3	3			3	2	3	3	3			3		3						34/38	12/16
PROSTATE	L	L	L	L	N	N	N	L	L	L	M	L	N	N	L							
Adenoma																					1/38	0/16
Leukemic infiltrates, monocytic	P																				0/38	1/16
Hyperplasia, adenomatous, focal															3						0/38	1/16
Inflammation, subacute, focal																					1/38	0/16
Inflammation, chronic-active		3	1					1	2	2											15/38	5/16
Inflammation, suppurative				1								2									0/38	2/16

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
EPIDIDYMIS	LL	NN	LL	LL	LL	NL	LL	LL	LL	NL	LL	LL	LL	NN	LL	LL	LL	LL	NN	LL
Spermatic granuloma(s), focal, unilateral/bilateral																				
Diminution of sperm in ducts, unilateral/bilateral																				
Absence of sperm in ducts, unilateral/bilateral	P		P	P	P	P	P	P	P	P	P	P	P		P	P	P	P		P
Cellular debris in ducts, unilateral/bilateral	P		P		P	P	P	P	P	P			P		P	P		P		P
SEMINAL VESICLE	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic						P														
URINARY BLADDER	L	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	L
Transitional cell carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P					P														
Lymphoid aggregates, submucosal, focal																				1

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
EPIDIDYMIS	NL	LL	LL	LL	NL	LL	LL	LL	LL	LL	LL	NL	LL	LL	LL	NN	NL	LL	LL	LL
Spermatic granuloma(s), focal, unilateral/bilateral																			3	
Diminution of sperm in ducts, unilateral/bilateral													3							2
Absence of sperm in ducts, unilateral/bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P
Cellular debris in ducts, unilateral/bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P
SEMINAL VESICLE	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic					P															
URINARY BLADDER	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Transitional cell carcinoma					P															
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic					P															
Lymphoid aggregates, submucosal, focal																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
EPIDIDYMIS	LL	LL	LL	NN	NN	NL	LL	LL	LL	LL	NM	NN	LL	NN	LL							
Spermatic granuloma(s), focal,																						
unilateral/bilateral																					0/38	1/17
Diminution of sperm in ducts,																						
unilateral/bilateral			2				2	2													1/38	4/17
Absence of sperm in ducts, unilateral/																						
bilateral	P	P	P			P	P		P	P			P		P						34/38	11/17
Cellular debris in ducts, unilateral/																						
bilateral	P	P				P	P		P	P					P						30/38	9/17
SEMINAL VESICLE	L	N	N	N	N	N	N	N	N	L	M	N	N	N	N							
Leukemic infiltrates, lymphocytic										P											0/38	1/16
Leukemic infiltrates, monocytic	P																				2/38	1/16
URINARY BLADDER	N	N	N	N	N	N	N	N	N	L	M	N	N	N	N							
Transitional cell carcinoma																					1/38	0/16
Leukemic infiltrates, lymphocytic										P											0/38	1/16
Leukemic infiltrates, monocytic																					3/38	0/16
Lymphoid aggregates, submucosal, focal																					1/38	0/16

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LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Alveolar adenoma																				
Bronchiolar-alveolar adenoma											P									
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P	P				P						P			P		P			P
Adenomatosis, focus																				
Alveolar macrophages, focal/multifocal/																				
diffuse							3				3									
Lymphoid infiltrates,																				
peribronchial/iolar, focal	2	2	2	1	2	2		2	2	2	2	2	2	2	2	2	2	2	1	1
Hemorrhage, focal/multifocal							2													
Osseous metaplasia, focal/multifocal						3	1													
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	N	N	N	L	N	N	N	N	N	N	L	L	N	L	N	N	N	N	N	L
Inflammation, chronic											1	1		1						1
Mucocele(s), submucosal, focal				3																

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Alveolar adenoma												P								
Bronchiolar-alveolar adenoma																				
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic			P		P		P			P						P				P
Adenomatosis, focus																				
Alveolar macrophages, focal/multifocal/ diffuse		2																	2	
Lymphoid infiltrates, peribronchial/iolar, focal	1	2	1	2	2	2	2	1	1	2	2	2	2	2	2	1	2	1	2	2
Hemorrhage, focal/multifocal																				
Osseous metaplasia, focal/multifocal																				
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	L	N	N	L	N	L	L	N	N	N	N	N	N	L	L	N	L	N	N	N
Inflammation, chronic	1					1	2								1		2			
Mucocele(s), submucosal, focal				2										3						

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Alveolar adenoma																					1/38	0/17
Bronchiolar-alveolar adenoma																					1/38	0/17
Leukemic infiltrates, lymphocytic		P							P	P			P	P	P						1/38	6/17
Leukemic infiltrates, monocytic	P						P	P													12/38	4/17
Adenomatosis, focus							P														0/38	1/17
Alveolar macrophages, focal/multifocal/																						
diffuse																					3/38	1/17
Lymphoid infiltrates,																						
peribronchial/iolar, focal	2	1	1	2	2	2	2	2	2	1	1	2	2	1	1						37/38	17/17
Hemorrhage, focal/multifocal																					1/38	0/17
Osseous metaplasia, focal/multifocal																					2/38	0/17
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N							
TRACHEA	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N							
Inflammation, chronic						1															9/38	1/17
Mucocele(s), submucosal, focal																					3/38	0/17

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ORGAN / Lesion — Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
THYROID	NN	NN	LL	NN	NL	NN	NN	NL	NN	NN	NL	LL	LL	NN	NN	LL	NN	NN	LL	NL
C-cell adenoma, unilateral								P											P	
Follicular cystadenoma, unilateral/																				
bilateral													P			P			P	
Leukemic infiltrates, lymphocytic,																				
bilateral																				
Hyperplasia, C-cell, unilateral/																				
bilateral, focal			2		2											2				1
Cystic follicle(s), unilateral/bilateral											P	P	P						P	
PARATHYROID	NN	NN	MM	NN	NM	NN	NN	NL	NN	NN	NN	NN	NN	NN	NM	LL	NM	NN	NM	NN
Adenoma, unilateral/bilateral								P												
Hyperplasia, unilateral/bilateral																2				
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P					P											P			
Myocarditis, chronic, focal/multifocal	2	1	2	1	1		1	1	1	1	2	1	2	1	2	2	1	1	2	1
Auricular thrombosis																	P			

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
THYROID	NL	NN	LL	NN	NN	NL	NL	NL	NN	NL	NN	NN	NN	NN	NL	LL	LL	NN	LL	NN
C-cell adenoma, unilateral										P							P			
Follicular cystadenoma, unilateral/																				
bilateral																				
Leukemic infiltrates, lymphocytic,																				
bilateral																				
Hyperplasia, C-cell, unilateral/																				
bilateral, focal			2			2										1				
Cystic follicle(s), unilateral/bilateral	P		P			P	P	P							P		P		P	
PARATHYROID	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NM	NM	NM	NL	NM	NN
Adenoma, unilateral/bilateral																				
Hyperplasia, unilateral/bilateral																		2		
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic					P											P				P
Myocarditis, chronic, focal/multifocal	2	2	2	2	2	2	1	1	2	2	1	2	2	2	1	1	1	1	2	2
Auricular thrombosis																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
THYROID	NN	NL	NN	NN	NN	NN	NL	NN	NN	NN	NL	NL	NM	LL	NN							
C-cell adenoma, unilateral							P				P	P		P							4/38	4/17
Follicular cystadenoma, unilateral/																						
bilateral																					3/38	0/17
Leukemic infiltrates, lymphocytic,																						
bilateral														P							0/38	1/17
Hyperplasia, C-cell, unilateral/																						
bilateral, focal		2																			7/38	1/17
Cystic follicle(s), unilateral/bilateral																					11/38	1/17
PARATHYROID	NN	NN	NN	NN	NN	NN	NM	NM	NN	NN	NN	NN	NM	NN	NM							
Adenoma, unilateral/bilateral																					1/37	0/17
Hyperplasia, unilateral/bilateral																					2/37	0/17
HEART	L	L	L	L	L	N	L	L	L	L	L	L	L	L	N							
Leukemic infiltrates, lymphocytic		P								P				P							1/38	3/17
Leukemic infiltrates, monocytic																					5/38	1/17
Myocarditis, chronic, focal/multifocal	2		2	1	2		2	2	1		2	1	1								37/38	12/17
Auricular thrombosis									P												1/38	1/17

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RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule											P									
Hepatocellular carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P	P			P	P	P	P	P	P		P	P		P		P		P	
Focus/foci of hyperplasia with cystic degeneration			P						P				P			P				
Area(s) of hyperplasia with cystic degeneration	P							P		P							P			P
Foci of cellular alteration-basophilic	P	P	P	P	P		P	P	P	P	P	P	P	P	P	P		P	P	
Foci of cellular alteration-eosinophilic																				
Area of cellular alteration-clear cells																				
Foci of cellular alteration-mixed cells		P	P					P	P	P	P	P	P		P					P
Necrosis, random, focal					1															
Necrosis, liquefaction, focal/multifocal																				
Necrosis, centrilobular, agonal, focal/multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal/diffuse	3	2	2	2	2	2	3	3	2	2	2	2	1	2	2	2	3	1	2	2

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule		P	P																	
Hepatocellular carcinoma																				
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic			P		P		P			P	P	P	P	P	P	P	P			P
Focus/foci of hyperplasia with cystic degeneration														P						
Area(s) of hyperplasia with cystic degeneration				P	P					P	P					P				
Foci of cellular alteration-basophilic	P	P			P	P	P	P		P	P	P	P			P	P			
Foci of cellular alteration-eosinophilic			P				P	P	P		P						P			
Area of cellular alteration-clear cells													P							
Foci of cellular alteration-mixed cells		P		P		P						P								
Necrosis, random, focal									3											
Necrosis, liquefaction, focal/multifocal																				
Necrosis, centrilobular, agonal, focal/multifocal/diffuse																			3	
Bile duct proliferation, focal/ multifocal/diffuse	2	2	2	2	3	2	2	2	2	2	3	2	2	2	1	2	2	3	2	3

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
LIVER	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L							
Neoplastic nodule	P																				3/38	1/17
Hepatocellular carcinoma										P											0/38	1/17
Leukemic infiltrates, lymphocytic		P							P				P	P	P						1/38	5/17
Leukemic infiltrates, monocytic	P						P	P													24/38	4/17
Focus/foci of hyperplasia with cystic degeneration																					5/38	0/17
Area(s) of hyperplasia with cystic degeneration																					10/38	0/17
Foci of cellular alteration-basophilic	P	P																			29/38	2/17
Foci of cellular alteration-eosinophilic																					6/38	0/17
Area of cellular alteration-clear cells																					1/38	0/17
Foci of cellular alteration-mixed cells																					14/38	0/17
Necrosis, random, focal																					2/38	0/17
Necrosis, liquefaction, focal/multifocal															3						0/38	1/17
Necrosis, centrilobular, agonal, focal/multifocal/diffuse											2										0/38	2/17
Bile duct proliferation, focal/ multifocal/diffuse		2	2	2		1	3	3		3	2	2	3	2	3						38/38	14/17

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
LIVER (continued)																				
Cholangiofibrosis, focal/multifocal	2	2			2	2	2	2		2		2		2	2		2		2	2
Metamorphosis, fatty, periportal/ centrilobular/random, focal/ multifocal/diffuse																				
Mononuclear cell infiltrates, sinusoidal, diffuse																				1
Extramedullary hematopoiesis, focal/ multifocal																		1		
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic, unilateral/bilateral																				
Leukemic infiltrates, monocytic, bilateral	P					P														
Nephropathy, chronic, bilateral	3	3	3	2	2	3	3	3	3	3	3	3	3	3	3	4	2	3	3	3
Inflammation, lymphocytic, bilateral	2	2	2	1	2	2	2	1	2	1	2	2	2	2	2	2	1	2	2	2
Cortex, increased pigment, bilateral							1													
Cortex, protein resorption droplets, bilateral																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
LIVER (continued)																				
Cholangiofibrosis, focal/multifocal	2	2	2	2	3	2	2	2		2	2	1	2			2	2			2
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Mononuclear cell infiltrates,																				
sinusoidal, diffuse																				
Extramedullary hematopoiesis, focal/																				
multifocal																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																		P		
Leukemic infiltrates, monocytic,																				
bilateral					P															P
Nephropathy, chronic, bilateral	2	3	2	3	2	2	3	2	2	2	3	3	2	3	2	3	3	2	3	2
Inflammation, lymphocytic, bilateral	1	2	1	2	1	2	2	1	1	1	2	2	1	2	1	2	2	1	1	
Cortex, increased pigment, bilateral															1					
Cortex, protein resorption droplets,																				
bilateral																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Cholangiofibrosis, focal/multifocal	3	2		2				2	3	2			2								27/38	8/17
Metamorphosis, fatty, periportal/																						
centrilobular/random, focal/																						
multifocal/diffuse							3							3	2						0/38	3/17
Mononuclear cell infiltrates,																						
sinusoidal, diffuse																					1/38	0/17
Extramedullary hematopoiesis, focal/																						
multifocal																					1/38	0/17
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL							
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral		P							P	P			P	P							1/38	5/17
Leukemic infiltrates, monocytic,																						
bilateral																					3/38	1/17
Nephropathy, chronic, bilateral	3	2	2	2	3	2	2	2	3	2	2	2	2	2	2						38/38	17/17
Inflammation, lymphocytic, bilateral	1	2		1		1		1	2	1		1	1		1						38/38	11/17
Cortex, increased pigment, bilateral		2					2	2		2	3			1	2						2/38	7/17
Cortex, protein resorption droplets,																						
bilateral													3								0/38	1/17

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
KIDNEY (continued)																				
Mineralization, uremic, bilateral																				
Cyst, cortical, unilateral									P											
STOMACH	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Mucosal ulcer(s), forestomach																				
Microgranuloma, forestomach																				
Mucosal ulcer(s), glandular region																				
Mucosal erosion(s), glandular region																				
Mineralization, uremic																				
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
KIDNEY (continued)																				
Mineralization, uremic, bilateral																	1			
Cyst, cortical, unilateral																				
STOMACH	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic					P															
Mucosal ulcer(s), forestomach																				
Microgranuloma. forestomach																				
Mucosal ulcer(s), glandular region																				
Mucosal erosion(s), glandular region																				
Mineralization, uremic																	2			
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
KIDNEY (continued)																						
Mineralization, uremic, bilateral																					1/38	0/17
Cyst, cortical, unilateral																					1/38	0/17
STOMACH	N	N	N	N	N	N	L	N	N	L	N	N	L	L	L							
Leukemic infiltrates, lymphocytic										P				P							0/38	2/17
Leukemic infiltrates, monocytic							P														1/38	1/17
Mucosal ulcer(s), forestomach															2						0/38	1/17
Microgranuloma, forestomach							2														0/38	1/17
Mucosal ulcer(s), glandular region													1		2						0/38	2/17
Mucosal erosion(s), glandular region							1														0/38	1/17
Mineralization, uremic																					1/38	0/17
DUODENUM	I	N	N	N	N	N	N	N	N	N	N	N	N	L	N							
Leukemic infiltrates, lymphocytic														P							0/38	1/16
JEJUNUM	I	I	N	N	N	N	N	N	N	N	N	N	N	N	N							
ILEUM	I	I	N	N	N	N	N	N	N	N	N	N	N	L	N							
Leukemic infiltrates, lymphocytic														P							0/38	1/15

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
CECUM	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N
Nematode parasites in lumen												P								
Inflammation with ulceration																				
Mineralization, uremic																				
COLON	L	L	N	L	N	L	L	N	N	N	N	L	N	N	L	N	N	N	N	L
Leukemic infiltrates, monocytic																				
Nematode parasites in lumen	P	P		P		P	P					P			P					P
RECTUM	N	N	N	N	N	N	N	N	N	N	L	N	N	L	L	N	N	N	N	N
Nematode parasites in lumen											P			P	P					
SKIN	N	N	N	N	N	L	L	N	N	L	N	L	L	N	N	N	N	N	N	N
Dermal fibroma							P			P										
Keratoacanthoma												P								
Papilloma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic						P														
Inflammation, chronic, focal													1							

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ORGAN / Lesion — Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
CECUM	N	L	N	N	N	N	N	N	N	L	N	N	N	N	L	N	L	N	N	N
Nematode parasites in lumen		P								P					P					
Inflammation with ulceration																				
Mineralization, uremic																	1			
COLON	N	N	N	N	L	N	N	N	N	N	L	L	L	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic					P															
Nematode parasites in lumen											P	P	P							
RECTUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Nematode parasites in lumen																				
SKIN	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Dermal fibroma						P														
Keratoacanthoma																				
Papilloma						P														
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Inflammation, chronic, focal																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
CECUM	I	L	N	N	N	N	N	N	N	N	L	N	N	L	N							
Nematode parasites in lumen		P									P										4/38	2/16
Inflammation with ulceration														4							0/38	1/16
Mineralization, uremic																					1/38	0/16
COLON	I	N	N	N	N	N	N	L	N	L	N	N	N	N	N							
Leukemic infiltrates, monocytic																					1/38	0/16
Nematode parasites in lumen								P		P											11/38	2/16
RECTUM	I	N	N	N	N	N	N	N	N	N	N	N	N	N	N							
Nematode parasites in lumen																					3/38	0/16
SKIN	L	L	N	L	N	N	N	N	N	L	N	N	L	L	N							
Dermal fibroma																					3/38	0/17
Keratoacanthoma																					1/38	0/17
Papilloma				P																	1/38	1/17
Leukemic infiltrates, lymphocytic		P								P			P	P							0/38	4/17
Leukemic infiltrates, monocytic	P																				1/38	1/17
Inflammation, chronic, focal																					1/38	0/17

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
MAMMARY GLAND	L	M	N	N	N	N	N	N	N	L	N	N	N	L	N	N	N	N	L	N
Fibroadenoma																			P	
Galactoceles	P									P				P					P	
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic						P														
Myelofibrosis, focal																				2
Hypocellular																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND	L																			
Dacryoadenitis, unilateral	1																			
ZYMBAL'S GLAND																				
Carcinoma																				

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ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
MAMMARY GLAND	N	N	N	N	N	L	N	N	N	N	N	N	L	N	N	N	L	N	N	N
Fibroadenoma						P														
Galactoceles													P				P			
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				P
Myelofibrosis, focal																				
Hypocellular														2						
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND																				
Dacryoadenitis, unilateral																				
ZYMBAL'S GLAND	L																			
Carcinoma	P																			

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
MAMMARY GLAND	N	L	N	L	L	N	N	N	M	N	N	N	N	N	N							
Fibroadenoma																					2/37	0/16
Galactoceles		P		P	P																6/37	3/16
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N							
BONE MARROW	I	L	N	N	N	N	N	N	N	L	N	N	N	L	N							
Leukemic infiltrates, lymphocytic		P								P				P							0/38	3/16
Leukemic infiltrates, monocytic																					1/38	1/16
Myelofibrosis, focal																					1/38	0/16
Hypocellular																					1/38	0/16
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP																						
HARDERIAN GLAND																						
Dacryoadenitis, unilateral																					1/1	-
ZYMBAL'S GLAND																						
Carcinoma																					1/1	-

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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY				L							L			L						L
Mesothelioma, (multiple																				
sites)																				
Leukemic infiltrates, lymphocytic																				
Lipogranuloma/fat necrosis				P							P			P						P
COAGULATING GLAND		L																		
Spermatic granuloma(s), focal		1																		
PREPUTIAL GLAND											L			L						
Carcinoma														P						
Adenoma											P									
Abscess																				
THYMUS						L														
Monocytic leukemia						P														
Malignant lymphoma																				
LYMPH NODE(S), NOS	L			L		L	L													
Monocytic leukemia	P					P	P													
Malignant lymphoma																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY	L		L	L						L						L		L		
Mesothelioma, (multiple																				
sites)																				
Leukemic infiltrates, lymphocytic																				
Lipogranuloma/fat necrosis	P		P	P						P						P		P		
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND												L	L							
Carcinoma													P							
Adenoma																				
Abscess												P								
THYMUS																				
Monocytic leukemia																				
Malignant lymphoma																				
LYMPH NODE(S), NOS					L															
Monocytic leukemia					P															
Malignant lymphoma																				

continued next page

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP (continued)																						
MESENTERY/ABDOMINAL CAVITY	L	L									L			L								
Mesothelioma, (multiple																						
sites)											P										0/10	1/4
Leukemic infiltrates, lymphocytic														P							0/10	1/4
Lipogranuloma/fat necrosis	P	P												P							10/10	3/4
COAGULATING GLAND																						
Spermatic granuloma(s), focal																					1/1	-
PREPUTIAL GLAND													L									
Carcinoma																					2/4	0/1
Adenoma													P								1/4	1/1
Abscess																					1/4	0/1
THYMUS	L	L						L		L			L									
Monocytic leukemia	P							P													1/1	2/5
Malignant lymphoma		P								P			P								0/1	3/5
LYMPH NODE(S), NOS		L						L	L		L		L	L	L							
Monocytic leukemia								P													4/5	1/7
Malignant lymphoma		P							P				P	P	P						0/5	5/7

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6512	80-6513	80-6518	80-6519	80-6520	80-6521	80-6522	80-6523	80-6524	80-6527	80-6529	80-6532	80-6534	80-6538	80-6539	80-6541	80-6543	80-6544	80-6546	80-6550
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Hyperplasia, lymphoid and plasma cell				3																
Angiectasis																				
PENIS																				

continued
next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6551	80-6552	80-6553	80-6554	80-6556	80-6559	80-6560	80-6564	80-6565	80-6566	80-6573	80-6576	80-6577	80-6578	80-6579	80-6580	80-6581	80-6582	80-6511*	80-6548*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Hyperplasia, lymphoid and plasma cell																				
Angiectasis																				
PENIS																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6558*	80-6561*	80-6562*	80-6567*	80-6570*	80-6508**	80-6514**	80-6515**	80-6533**	80-6535**	80-6536**	80-6547**	80-6549**	80-6563**	80-6575**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP (continued)																						
LYMPH NODE(S), NOS (continued)																						
Hyperplasia, lymphoid and plasma cell																					1/5	0/7
Angiectasis											2										0/5	1/7
PENIS			N																			

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
PITUITARY	L	N	L	L	L	L	L	N	L	N	L	N	L	L	N	L	L	L	L	L
Adenoma	P		P				P		P				P	P			P		P	P
Carcinoma											P									
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Cyst				P	P	P														
Hyperplasia, basophil-cell																				
Hyperplasia, chromophobe-cell																1		1		
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule						P		P												
Malignant fibrous histiocytoma																				

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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	N	L	L	L	L	L	L	L	N	L	L	L	N	N
Adenoma	P	P	P	P	P	P		P	P	P	P	P		P		P		P		
Carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																	P			
Cyst													P							
Hyperplasia, basophil-cell																				
Hyperplasia, chromophobe-cell																				
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule		P																		
Malignant fibrous histiocytoma						P														

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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	L	N	L	L							
Leukemic infiltrates, lymphocytic												P		P	P						0/36	3/19
Hemorrhage, focal												3			2						0/36	2/19
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	L	N	N	L							
Leukemic infiltrates, lymphocytic												P			P						0/36	2/19
Hemorrhage, focal												3			2						0/36	2/19
PITUITARY	N	L	L	L	N	L	N	L	M	L	N	L	L	N	L							
Adenoma			P							P											22/36	3/18
Carcinoma																					1/36	0/18
Leukemic infiltrates, lymphocytic		P		P								P	P								0/36	4/18
Leukemic infiltrates, monocytic								P													0/36	2/18
Cyst						P															4/36	1/18
Hyperplasia, basophil-cell													1								0/36	1/18
Hyperplasia, chromophobe-cell				1				1							1						2/36	3/18
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Neoplastic nodule																					3/36	0/19
Malignant fibrous histiocytoma																					1/36	0/19

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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
LIVER (continued)																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P	P		P	P	P	P	P		P		P	P	P		P	P	P		P
Focus/foci of hyperplasia with cystic degeneration											P									
Area(s) of hyperplasia with cystic degeneration			P									P	P	P				P		
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic	P	P				P		P	P	P		P	P		P				P	P
Area of cellular alteration-clear cells																				
Foci of cellular alteration-mixed cells					P												P			
Necrosis, random, focal							2													
Necrosis, liquefaction, focal/multifocal																				
Necrosis, centrilobular, agonal, focal/ multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal/diffuse	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Cholangiofibrosis, focal/multifocal	2			2	2	2	2		1	1	2	2	2		2			2	1	1
Metamorphosis, fatty, random, focal/ multifocal/diffuse			1							2										

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FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
LIVER (continued)																				
Leukemic infiltrates, lymphocytic														P						
Leukemic infiltrates, monocytic		P	P		P	P	P	P		P			P		P	P	P			P
Focus/foci of hyperplasia with cystic																				
degeneration								P	P											
Area(s) of hyperplasia with cystic																				
degeneration			P		P					P				P						
Foci of cellular alteration-basophilic	P	P			P	P			P	P		P		P	P			P		
Foci of cellular alteration-eosinophilic	P				P	P	P					P		P	P					
Area of cellular alteration-clear cells											P									
Foci of cellular alteration-mixed cells		P		P																
Necrosis, random, focal																				
Necrosis, liquefaction, focal/multifocal																				1
Necrosis, centrilobular, agonal, focal/																				
multifocal/diffuse																	2			
Bile duct proliferation, focal/																				
multifocal/diffuse	2	3	3	2	2	2	2	3	2	2	2	2	2	3	2	2	2		2	3
Cholangiofibrosis, focal/multifocal	2		2		2	2	2	2	2	2		2	2	2		1	3			2
Metamorphosis, fatty, random, focal/																				
multifocal/diffuse				2														3		

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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Leukemic infiltrates, lymphocytic		P		P									P	P	P						1/36	5/19
Leukemic infiltrates, monocytic	P							P													25/36	4/19
Focus/foci of hyperplasia with cystic degeneration																					3/36	0/19
Area(s) of hyperplasia with cystic degeneration	P																				9/36	1/19
Foci of cellular alteration-basophilic			P		P																29/36	3/19
Foci of cellular alteration-eosinophilic			P																		18/36	1/19
Area of cellular alteration-clear cells																					1/36	0/19
Foci of cellular alteration-mixed cells																					4/36	0/19
Necrosis, random, focal		3																			1/36	1/19
Necrosis, liquefaction, focal/multifocal																					0/36	1/19
Necrosis, centrilobular, agonal, focal/ multifocal/diffuse	3			1	2							2									0/36	5/19
Bile duct proliferation, focal/ multifocal/diffuse	3	3	1	1	1	1	1	3	2	1	2	3	3	2	2						36/36	18/19
Cholangiofibrosis, focal/multifocal	2	3		2				2			2	2	2	2	2						26/36	11/19
Metamorphosis, fatty, random, focal/ multifocal/diffuse								2		1	2		2	2							3/36	6/19

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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Hemangioma																				
Leukemic infiltrates, lymphocytic, unilateral/bilateral																				
Leukemic infiltrates, monocytic, bilateral																				
Nephropathy, chronic, bilateral	4	3	3	2	3	3	3	3	2	2	2	3	2	3	3	2	3	3	2	2
Inflammation, lymphocytic, bilateral	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	1	1
Pyelitis, suppurative, unilateral/ bilateral																				
Cortex, increased pigment, bilateral	2						2													1
Cortex, protein resorption droplets, bilateral														2						
Necrosis, medullary papilla, unilateral/ bilateral																				
Mineralization, uremic, bilateral																				
Cyst, cortical, unilateral									P											

continued next page

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Hemangioma																		P		
Leukemic infiltrates, lymphocytic, unilateral/bilateral																				
Leukemic infiltrates, monocytic, bilateral																	P			
Nephropathy, chronic, bilateral	2	3	3	4	3	3	3	2	2	2	2	2	3	2	3	3	2	4	2	2
Inflammation, lymphocytic, bilateral	2	2	2	2	2	2	2	2	2	2	1	1	2	1	2	2		1		1
Pyelitis, suppurative, unilateral/bilateral																				
Cortex, increased pigment, bilateral										2										2
Cortex, protein resorption droplets, bilateral								2						1						
Necrosis, medullary papilla, unilateral/bilateral																				
Mineralization, uremic, bilateral																				
Cyst, cortical, unilateral																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL							
Hemangioma																					0/36	1/19
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral		P		P								P	P	P							0/36	5/19
Leukemic infiltrates, monocytic,																						
bilateral																					0/36	1/19
Nephropathy, chronic, bilateral	3	3	2	3	2	2	2	2	1	2	2	2	2	2	3						36/36	19/19
Inflammation, lymphocytic, bilateral	2		1			1		2		1					1						36/36	8/19
Pyelitis, suppurative, unilateral/																						
bilateral							3														0/36	1/19
Cortex, increased pigment, bilateral								3													4/36	2/19
Cortex, protein resorption droplets,																						
bilateral												2									3/36	1/19
Necrosis, medullary papilla, unilateral/																						
bilateral							P														0/36	1/19
Mineralization, uremic, bilateral							2														0/36	1/19
Cyst, cortical, unilateral																					1/36	0/19

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
HEART	L	L	N	L	N	N	L	L	L	L	L	L	L	L	L	L	L	N	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				P
Myocarditis, chronic, focal/multifocal	1	1		2			2	2	1	1	2	2	1	1	2	2	1		1	
Auricular thrombosis																				
Mineralization, vessels, uremic																				
Mineralization, myocardial, uremic																				
SPLEEN	L	L	N	L	L	L	L	L	N	L	L	L	L	L	N	L	L	L	L	L
Malignant lymphoma																				
Histiocytic sarcoma					P															
Monocytic leukemia	P	P		P	P	P	P	P		P		P	P	P		P	P	P		P
Congestion, diffuse											1								1	
Fibrosis, focal													1				1			
Increased extramedullary hematopoiesis													1			1				
Increased pigment, diffuse																				
Infarction, focal/multifocal																				
Osseous metaplasia, focal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
HEART	L	L	L	N	L	N	L	L	L	L	L	N	L	L	L	N	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	2	1		1		1	1	1	1	1		2	1	1		2	2	2	2
Auricular thrombosis																				
Mineralization, vessels, uremic																				
Mineralization, myocardial, uremic																				
SPLEEN	N	L	L	N	L	L	L	L	N	L	L	N	L	L	N	L	L	L	N	L
Malignant lymphoma														P						
Histiocytic sarcoma																				
Monocytic leukemia		P	P		P	P	P	P		P			P			P	P			P
Congestion, diffuse																				
Fibrosis, focal		3						2					1							
Increased extramedullary hematopoiesis											1							2		
Increased pigment, diffuse																				
Infarction, focal/multifocal																				
Osseous metaplasia, focal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
HEART	L	L	L	N	N	L	L	L	N	L	N	L	L	L	N							
Leukemic infiltrates, lymphocytic												P	P	P							0/36	3/19
Leukemic infiltrates, monocytic		P																			1/36	1/19
Myocarditis, chronic, focal/multifocal	2		1			1		2		1											27/36	9/19
Auricular thrombosis	P																				0/36	1/19
Mineralization, vessels, uremic							3														0/36	1/19
Mineralization, myocardial, uremic							2														0/36	1/19
SPLEEN	L	L	N	L	L	L	L	L	L	L	N	L	L	L	L							
Malignant lymphoma		P		P								P	P	P	P						1/36	6/19
Histiocytic sarcoma																					1/36	0/19
Monocytic leukemia	P							P													24/36	4/19
Congestion, diffuse																					2/36	0/19
Fibrosis, focal																					5/36	0/19
Increased extramedullary hematopoiesis					2	1	1		3												3/36	5/19
Increased pigment, diffuse										2											0/36	1/19
Infarction, focal/multifocal								2				3									0/36	2/19
Osseous metaplasia, focal													2								0/36	1/19

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Capsule/NOS, mesothelioma,																				
unilateral/bilateral	P						P													
Interstitial cell tumor, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral											2									
Hypospermatogenesis, multifocal/diffuse,																				
unilateral/bilateral																				
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral						3				3			3		2					
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
PROSTATE	N	N	L	L	N	N	N	N	N	L	L	L	L	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hyperplasia, adenomatous, focal													2							
Inflammation, chronic-active			2	1						1	2	1	1							

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
TESTIS	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	LL	LL	LL	NL	LL	LL	LL	LL	LL	LL
Capsule/NOS, mesothelioma,																				
unilateral/bilateral																				
Interstitial cell tumor, unilateral/																				
bilateral	P	P	P	P	P		P	P	P		P	P	P	P	P	P	P	P	P	P
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral										2		2								
Hypospermatogenesis, multifocal/diffuse,																				
unilateral/bilateral		4																		
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral				2				3	2				3		3				3	3
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3		2	3		3	3	3		3	3	3	3	3	3	3	3	3	
PROSTATE	N	L	L	L	N	N	N	N	N	L	N	L	L	L	N	L	N	L	N	L
Leukemic infiltrates, lymphocytic																				
Hyperplasia, adenomatous, focal																				
Inflammation, chronic-active		1	1	1								2	1	1		2		1		

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T = terminal sacrifice S = [illegible] death

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
TESTIS	LL	LL	NN	NL	LL	LL	LL	LL	LL	NL	LL	LL	LL	LL	LL							
Capsule/NOS, mesothelioma, unilateral/bilateral																					2/36	0/19
Interstitial cell tumor, unilateral/bilateral	P	P		P	P	P		P	P		P	P		P	P						34/36	15/19
Hyperplasia, interstitial cell, focal, unilateral/bilateral							2		2				2								3/36	3/19
Hypospermatogenesis, multifocal/diffuse, unilateral/bilateral											3			3							1/36	2/19
Germinal cell degeneration, focal/multifocal/diffuse, unilateral/bilateral		3						3	3	3					3						9/36	7/19
Tubules, atrophy, compression, focal/multifocal/diffuse, unilateral/bilateral	3	3		3	3	3					3	3		3	3						33/36	12/19
PROSTATE	N	L	N	N	N	N	L	L	N	L	L	N	L	N	L							
Leukemic infiltrates, lymphocytic		P																			0/36	1/19
Hyperplasia, adenomatous, focal																					1/36	0/19
Inflammation, chronic-active								1			1		2		1						13/36	5/19

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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PROSTATE (continued)																				
Inflammation, suppurative																				
Microabscesses																				
EPIDIDYMIS	LL	LM	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Capsule, mesothelioma, unilateral/																				
bilateral	P						P													
Spermatic granuloma(s), focal,																				
unilateral/bilateral															2					
Diminution of sperm in ducts,																				
unilateral/bilateral			2							3	3		3		3					
Absence of sperm in ducts, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P			P	P	P	P	P	P		P	P
Cellular debris in ducts, unilateral/																				
bilateral			P	P	P	P	P	P	P	P	P	P	P	P	P		P		P	P
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Distended with secretion																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
PROSTATE (continued)																				
Inflammation, suppurative										3										3
Microabscesses																				
EPIDIDYMIS	LL	LL	LL	LL	LL	NN	LL	LL	LL	NN	LL	LL	NN	NL	NN	LL	LL	LL	LL	LL
Capsule, mesothelioma, unilateral/																				
bilateral																				
Spermatic granuloma(s), focal,																				
unilateral/bilateral																				
Diminution of sperm in ducts,																				
unilateral/bilateral				1					2			2								
Absence of sperm in ducts, unilateral/																				
bilateral	P	P	P		P		P	P	P		P			P		P		P	P	P
Cellular debris in ducts, unilateral/																				
bilateral	P		P		P		P	P	P		P	P		P		P	P	P		P
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Distended with secretion																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
PROSTATE (continued)																						
Inflammation, suppurative							4			3											1/36	3/19
Microabscesses										P											0/36	1/19
EPIDIDYMIS	NN	LL	NN	NL	NL	LL	NN	LL	NL	NL	LL	LL	NL	LL	NL							
Capsule, mesothelioma, unilateral/ bilateral																					2/36	0/19
Spermatic granuloma(s), focal, unilateral/bilateral					1																1/36	1/19
Diminution of sperm in ducts, unilateral/bilateral						3					2	2	2	3	3						8/36	6/19
Absence of sperm in ducts, unilateral/ bilateral		P		P	P	P		P	P	P		P		P							27/36	12/19
Cellular debris in ducts, unilateral/ bilateral				P		P			P	P	P			P	P						26/36	10/19
SEMINAL VESICLE	N	L	N	N	N	N	L	N	N	N	N	N	N	L	N							
Leukemic infiltrates, lymphocytic		P												P							0/36	2/19
Distended with secretion							P														0/36	1/19

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE							L						L							
Keratitis, chronic, unilateral/																				
bilateral, focal							3						4							
Lens, cataract, unilateral/bilateral																				
Lens-induced inflammation, unilateral							P													
ADRENAL											LL									
Pheochromocytoma, unilateral/																				
bilateral																				
Cortex, angiectasis, unilateral/																				
bilateral, focal											2									
PANCREAS	L																			
Leukemic infiltrates, lymphocytic																				
Capsule, mesothelioma	P																			
Hyperplasia, islet cell, focal																				
Atrophy, acinar cell, focal																				
MESENTERIC LYMPH NODE																				L
Monocytic leukemia																				P
Malignant lymphoma																				

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE																				
Keratitis, chronic, unilateral/																				
bilateral, focal																				
Lens, cataract, unilateral/bilateral																				
Lens-induced inflammation, unilateral																				
ADRENAL		L			L														L	
Pheochromocytoma, unilateral/																				
bilateral		P			P														P	
Cortex, angiectasis, unilateral/																				
bilateral, focal																				
PANCREAS														L						
Leukemic infiltrates, lymphocytic																				
Capsule, mesothelioma																				
Hyperplasia, islet cell, focal																				
Atrophy, acinar cell, focal														2						
MESENTERIC LYMPH NODE						L														
Monocytic leukemia						P														
Malignant lymphoma																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP																						
EYE													L									
Keratitis, chronic, unilateral/																						
bilateral, focal																					2/2	0/1
Lens, cataract, unilateral/bilateral													P								0/2	1/1
Lens-induced inflammation, unilateral																					1/2	0/1
ADRENAL	L																					
Pheochromocytoma, unilateral/																						
bilateral	P																				2/3	2/2
Cortex, angiectasis, unilateral/																						
bilateral, focal																					1/3	0/2
PANCREAS		L										L										
Leukemic infiltrates, lymphocytic		P																			0/2	1/2
Capsule, mesothelioma																					1/2	0/2
Hyperplasia, islet cell, focal												2									0/2	1/2
Atrophy, acinar cell, focal																					1/2	0/2
MESENTERIC LYMPH NODE		L		L				L					L									
Monocytic leukemia																					2/2	0/4
Malignant lymphoma		P		P									P								0/2	3/4

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERIC LYMPH NODE (continued)																				
Extramedullary hematopoiesis																				
URINARY BLADDER																				
Leukemic infiltrates, lymphocytic																				
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																				
LUNG-MAINSTEM BRONCHI																L		L		L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																		P		P
Alveolar macrophages, focal/multifocal/																				
diffuse																		2		2
Lymphoid infiltrates,																				
peribronchial/iolar, focal																2				
Hemorrhage, focal/multifocal																		1		
ESOPHAGUS																				
TRACHEA																				

continued next page

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RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERIC LYMPH NODE (continued)																				
Extramedullary hematopoiesis																				
URINARY BLADDER																			L	
Leukemic infiltrates, lymphocytic																				
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																			P	
LUNG-MAINSTEM BRONCHI								L			L							N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic								P												
Alveolar macrophages, focal/multifocal/																				
diffuse																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal											3									
Hemorrhage, focal/multifocal																				
ESOPHAGUS																				
TRACHEA																				

continued next page

de: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						IS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MESENTERIC LYMPH NODE (continued)																						
Extramedullary hematopoiesis								3													0/2	1/4
URINARY BLADDER							L		N	N			L		L							
Leukemic infiltrates, lymphocytic													P								-	1/6
Cystitis, hemorrhagic-suppurative							4								1						-	2/6
Distention, luminal							P														-	2/6
LUNG-MAINSTEM BRONCHI	L	L	N	L									L	L	L							
Leukemic infiltrates, lymphocytic		P		P									P	P	P						0/5	5/10
Leukemic infiltrates, monocytic	P																				3/5	1/10
Alveolar macrophages, focal/multifocal/																						
diffuse		2																			2/5	1/10
Lymphoid infiltrates,																						
peribronchial/iolar, focal																					2/5	0/10
Hemorrhage, focal/multifocal																					1/5	0/10
ESOPHAGUS				N																		
TRACHEA				N																		

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYROID																	L			
Hyperplasia, C-cell, unilateral/																				
bilateral, focal																	2			
STOMACH																				
DUODENUM																				
Mucosal ulcers, focal																				
JEJUNUM																				
CECUM																				
COLON																				
SKIN		N		L	L							L				L			L	
Dermal fibrosarcoma				P																
Dermal fibroma																P				
Basal cell tumor, benign																				
Keratoacanthoma												P								
Papilloma				P															P	
Epidermal inclusion cyst																				
Acanthosis					3															
Exudative crusts					P															

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYROID																				
Hyperplasia, C-cell, unilateral/																				
bilateral, focal																				
STOMACH																		N		
DUODENUM				L																
Mucosal ulcers, focal				3																
JEJUNUM																				
CECUM																			I	
COLON																			I	
SKIN	L		L					L						L	L					
Dermal fibrosarcoma																				
Dermal fibroma	P																			
Basal cell tumor, benign																				
Keratoacanthoma			P											P						
Papilloma																				
Epidermal inclusion cyst								P							P					
Acanthosis																				
Exudative crusts																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
THYROID	I																					
Hyperplasia, C-cell, unilateral/																						
bilateral, focal																					1/1	-
STOMACH																						
DUODENUM																						
Mucosal ulcers, focal																					1/1	-
JEJUNUM					I																	
CECUM						N																
COLON																						
SKIN				N	L	L		N		N			L									
Dermal fibrosarcoma																					1/11	0/6
Dermal fibroma					P								P								2/11	2/6
Basal cell tumor, benign						P															0/11	1/6
Keratoacanthoma																					3/11	0/6
Papilloma																					2/11	0/6
Epidermal inclusion cyst																					2/11	0/6
Acanthosis																					1/11	0/6
Exudative crusts																					1/11	0/6

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F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND												L			L					
Fibroadenoma												P								
Galactoceles															P					
STERNUM																				
BONE MARROW																				
Leukemic infiltrates, lymphocytic																				
MESENTERY/ABDOMINAL CAVITY	L						L			L										
Mesothelioma, malignant (multiple																				
sites)	P						P													
Lipogranuloma/fat necrosis										P										
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND						L			L					L						
Carcinoma														P						
Adenoma									P											
Inflammation						P														
Cysts						P														

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F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND				L																
Fibroadenoma																				
Galactoceles				P																
STERNUM																				
BONE MARROW																				
Leukemic infiltrates, lymphocytic																				
MESENTERY/ABDOMINAL CAVITY								L												
Mesothelioma, malignant (multiple																				
sites)																				
Lipogranuloma/fat necrosis								P												
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND																L				
Carcinoma																				
Adenoma																				
Inflammation																P				
Cysts																				

continued next page

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FINAL REPORT
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						IS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MAMMARY GLAND																						
Fibroadenoma																					1/3	-
Galactoceles																					2/3	-
STERNUM				N																		
BONE MARROW				L																		
Leukemic infiltrates, lymphocytic				P																	-	1/1
MESENTERY/ABDOMINAL CAVITY			N					L			L											
Mesothelioma, malignant (multiple																						
sites)																					2/4	0/3
Lipogranuloma/fat necrosis								P			P										2/4	2/3
COAGULATING GLAND							L						L		L							
Spermatic granuloma(s), focal							3						2		1						-	3/3
PREPUTIAL GLAND									L													
Carcinoma									P												1/4	1/1
Adenoma																					1/4	0/1
Inflammation																					2/4	0/1
Cysts																					1/4	0/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYMUS																				
Malignant lymphoma																				
Lymphoid hyperplasia																				
Atrophy with cysts																				
LYMPH NODE(S), NOS					L															
Monocytic leukemia					P															
Malignant lymphoma																				
SALIVARY GLAND																				
URETER																				
Dilatation, bilateral																				
Peritonitis, bilateral																				
SUBCUTIS		L																		
Lipoma		P																		
Liposarcoma																				
FEMUR/BONE																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYMUS																		L		L
Malignant lymphoma																				
Lymphoid hyperplasia																				2
Atrophy with cysts																		P		
LYMPH NODE(S), NOS														L			L			
Monocytic leukemia																	P			
Malignant lymphoma														P						
SALIVARY GLAND																				
URETER																				
Dilatation, bilateral																				
Peritonitis, bilateral																				
SUBCUTIS																			L	
Lipoma																				
Liposarcoma																			P	
FEMUR/BONE																				

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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
THYMUS		L		L										L								
Malignant lymphoma		P		P										P							-	3/5
Lymphoid hyperplasia																					-	1/5
Atrophy with cysts																					-	1/5
LYMPH NODE(S), NOS		L		L				L				L	L	L								
Monocytic leukemia								P													1/2	2/7
Malignant lymphoma		P		P								P	P	P							1/2	5/7
SALIVARY GLAND				N																		
URETER							L															
Dilatation, bilateral							P														-	1/1
Peritonitis, bilateral							P														-	1/1
SUBCUTIS																						
Lipoma																					1/1	0/1
Liposarcoma																					0/1	1/1
FEMUR/BONE				N																		

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F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PITUITARY	N	L	N	L	M	N	L	L	L	L	N	L	N	L	L	L	L	L	N	N
Adenoma				P				P	P	P		P		P	P	P		P		
Carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Cyst																				
Hyperplasia, basophil-cell																				
Hyperplasia, chromophobe-cell		1					2										1			
Bacteremia																				
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Histiocytic sarcoma																				
Leukemic infiltrates, lymphocytic		P							P											
Leukemic infiltrates, monocytic	P				P		P	P		P				P	P					P

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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N
Leukemic infiltrates, lymphocytic																		P		
Hemorrhage, focal																		2		
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PITUITARY	L	L	L	L	L	L	L	L	N	L	L	N	L	L	L	L	L	L	L	N
Adenoma	P	P	P	P	P			P			P			P	P	P	P		P	
Carcinoma						P	P													
Leukemic infiltrates, lymphocytic										P								P		
Leukemic infiltrates, monocytic													P							
Cyst				P						P										
Hyperplasia, basophil-cell																		1		
Hyperplasia, chromophobe-cell																				
Bacteremia													P							
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Histiocytic sarcoma										P										
Leukemic infiltrates, lymphocytic				P						P								P		P
Leukemic infiltrates, monocytic				P	P		P				P		P		P	P				

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**	TS Incidence	SDMS Incidence
BRAIN	N	N	L	N	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic													0/25	1/27
Hemorrhage, focal			2										0/25	2/27
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N		
PITUITARY	N	L	N	N	N	N	L	L	L	N	N	L		
Adenoma		P					P	P	P				14/24	11/27
Carcinoma													0/24	2/27
Leukemic infiltrates, lymphocytic													0/24	2/27
Leukemic infiltrates, monocytic												P	0/24	2/27
Cyst													1/24	1/27
Hyperplasia, basophil-cell													0/24	1/27
Hyperplasia, chromophobe-cell													3/24	0/27
Bacteremia													0/24	1/27
LIVER	L	L	L	L	L	L	L	L	L	L	L	L		
Histiocytic sarcoma													0/25	1/27
Leukemic infiltrates, lymphocytic				P									3/25	4/27
Leukemic infiltrates, monocytic			P			P				P	P	P	10/25	10/27

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F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
LIVER (continued)																				
Focus/foci of hyperplasia with cystic degeneration	P										P									
Area(s) of hyperplasia with cystic degeneration			P					P												
Foci of cellular alteration-basophilic		P	P	P	P	P	P	P			P		P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic			P			P	P	P						P		P	P	P		P
Area of cellular alteration-clear cells																				
Foci of cellular alteration-mixed cells											P	P								
Necrosis, random, focal															1					
Necrosis, centrilobular, agonal, focal/ multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal/diffuse	3	3	2	2	2	2	2	2	3	2	2	2	2	2	2	2	2	2	2	2
Cholangiofibrosis, focal/multifocal		2					1		2	3	2	1		2	2				2	2
Metamorphosis, fatty, centrilobular/ periportal/random, focal/ multifocal/diffuse																				
Extramedullary hematopoiesis, focal/ multifocal													1						1	

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F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
LIVER (continued)																				
Focus/foci of hyperplasia with cystic																				
degeneration																				
Area(s) of hyperplasia with cystic																				
degeneration			P	P																P
Foci of cellular alteration-basophilic	P	P	P	P		P	P	P					P				P		P	
Foci of cellular alteration-eosinophilic		P																		
Area of cellular alteration-clear cells																				
Foci of cellular alteration-mixed cells			P		P															
Necrosis, random, focal																				
Necrosis, centrilobular, agonal, focal/																				
multifocal/diffuse						3					2	2	2							
Bile duct proliferation, focal/																				
multifocal/diffuse	2	2		2	2	2	2	2	1	3	3	2		2	2	3	2	2	1	3
Cholangiofibrosis, focal/multifocal	2			2	2			2		2	2		3		2	2		1		2
Metamorphosis, fatty, centrilobular/																				
periportal/random, focal/																				
multifocal/diffuse								2								2				2
Extramedullary hematopoiesis, focal/																				
multifocal						2														2

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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
LIVER (continued)																						
Focus/foci of hyperplasia with cystic																						
degeneration																					2/25	0/27
Area(s) of hyperplasia with cystic																						
degeneration																					4/25	1/27
Foci of cellular alteration-basophilic							P		P												20/25	8/27
Foci of cellular alteration-eosinophilic							P														10/25	1/27
Area of cellular alteration-clear cells									P												0/25	1/27
Foci of cellular alteration-mixed cells																					4/25	0/27
Necrosis, random, focal																					1/25	0/27
Necrosis, centrilobular, agonal, focal/																						
multifocal/diffuse					1					2											0/25	6/27
Bile duct proliferation, focal/																						
multifocal/diffuse	2	2	2	3	2	2	2	1	2	3	3	2									24/25	26/27
Cholangiofibrosis, focal/multifocal	1		3			2	2			2	2										13/25	14/27
Metamorphosis, fatty, centrilobular/																						
periportal/random, focal/																						
multifocal/diffuse		2		3		3				3	2										0/25	8/27
Extramedullary hematopoiesis, focal/																						
multifocal					1																2/25	3/27

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
LIVER (continued)																				
Microgranulomas, focal/multifocal																				
Bacteremia																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
bilateral																				
Nephropathy, chronic, bilateral	3	3	3	3	2	3	3	3	2	3	3	3	2	2	3	3	2	3	3	3
Inflammation, lymphocytic, bilateral	1	1	1	2		1	2	2		2	2	2		1	1	2	2	2	2	2
Pyelonephritis, unilateral/bilateral																				
Cortex, increased pigment, bilateral		1			1															
Cortex, protein resorption droplets,																				
bilateral									3	2					1					
Mineralization, uremic, bilateral																				
Cyst, cortical, unilateral																				
Bacteremia, bilateral																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
LIVER (continued)																				
Microgranulomas, focal/multifocal																				
Bacteremia													P							
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic, unilateral/bilateral										P								P		P
Leukemic infiltrates, monocytic, bilateral																P				
Nephropathy, chronic, bilateral	2	3	2	3	3	3	2	3	2	2	3	1	2	2	3	2	3	3	4	3
Inflammation, lymphocytic, bilateral	1	2	1	2	1	2	1	1	1	1					1		1		1	1
Pyelonephritis, unilateral/bilateral											2									
Cortex, increased pigment, bilateral											1									
Cortex, protein resorption droplets, bilateral			1																	
Mineralization, uremic, bilateral																			2	
Cyst, cortical, unilateral						P														
Bacteremia, bilateral													P							

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
LIVER (continued)																						
Microgranulomas, focal/multifocal									1												0/25	1/27
Bacteremia																					0/25	1/27
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL										
Leukemic infiltrates, lymphocytic, unilateral/bilateral																					0/25	3/27
Leukemic infiltrates, monocytic, bilateral											P	P									0/25	3/27
Nephropathy, chronic, bilateral	2	3	2	2	2	2	3	2	3	2	2	1									25/25	27/27
Inflammation, lymphocytic, bilateral	1	1		1			2		2												22/25	14/27
Pyelonephritis, unilateral/bilateral			1																		0/25	2/27
Cortex, increased pigment, bilateral											2										2/25	2/27
Cortex, protein resorption droplets, bilateral					1																4/25	1/27
Mineralization, uremic, bilateral										2											0/25	2/27
Cyst, cortical, unilateral																					0/25	1/27
Bacteremia, bilateral																					0/25	1/27

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ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	2	2	2	2	2	1	2	2	2	2	2	1	2	1	1	1	2	2	2
Auricular thrombosis		P																		
Mineralization, vessels, uremic																				
Mineralization, myocardial, uremic																				
Bacteremia																				
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L
Malignant lymphoma		P							P											
Monocytic leukemia	P				P		P	P		P				P	P					P
Congestion, diffuse			1								1	1						1		
Fibrosis, focal															2					
Increased extramedullary hematopoiesis			1	1		1	2						2				1			
Increased pigment, diffuse					2						1	1				2	1			
Infarction, focal/multifocal									3											

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																		P		
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1	1	1	1	1	2	3	2	2	1	2	1	1	2	2	2			2
Auricular thrombosis												P				P				
Mineralization, vessels, uremic																			3	
Mineralization, myocardial, uremic																			3	
Bacteremia													P							
SPLEEN	L	L	L	L	L	L	L	N	N	L	L	L	L	N	L	L	N	L	N	L
Malignant lymphoma										P								P		P
Monocytic leukemia				P	P		P				P		P		P	P				
Congestion, diffuse																				
Fibrosis, focal	2														1					
Increased extramedullary hematopoiesis						3						2								
Increased pigment, diffuse	1	2																		
Infarction, focal/multifocal													3							

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
HEART	N	N	N	L	L	L	N	L	N	L	L	L										
Leukemic infiltrates, lymphocytic																					0/25	1/27
Leukemic infiltrates, monocytic										P		P									0/25	2/27
Myocarditis, chronic, focal/multifocal				1	2	1		2			1										25/25	18/27
Auricular thrombosis																					1/25	2/27
Mineralization, vessels, uremic																					0/25	1/27
Mineralization, myocardial, uremic																					0/25	1/27
Bacteremia																					0/25	1/27
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L										
Malignant lymphoma				P																	2/25	4/27
Monocytic leukemia	P		P			P				P	P	P									10/25	11/27
Congestion, diffuse																					4/25	0/27
Fibrosis, focal									2												2/25	2/27
Increased extramedullary hematopoiesis					3					2											6/25	4/27
Increased pigment, diffuse		2					2	2	2												7/25	4/27
Infarction, focal/multifocal											3										1/25	2/27

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Interstitial cell tumor, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral															2	2				
Hypospermatogenesis, multifocal/diffuse,																				
unilateral/bilateral																				
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral	3							3	2				3							
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3	3	3	3	3	3	3	3	3	3	3		3			3		3	3
Arteritis, chronic, focal, unilateral/																				
bilateral																3				
PROSTATE	N	L	N	N	N	N	N	N	N	L	N	L	N	N	L	L	N	L	N	N
Leukemic infiltrates, lymphocytic																				
Hyperplasia, adenomatous, focal																				
Inflammation, chronic-active		1								1		1			2			1		

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL	NL	LL	LL	LL	LL	LL	LL
Interstitial cell tumor, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P	P	P		P
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral						2													1	2
Hypospermatogenesis, multifocal/diffuse,																				
unilateral/bilateral						3											2			
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral							3	3										2	3	
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral		3	3	3	3	3	3	3	3	3	3		3		3	3	3	3		3
Arteritis, chronic, focal, unilateral/																				
bilateral						1														
PROSTATE	N	N	L	N	L	N	L	N	L	N	N	N	N	L	L	N	L	L	N	L
Leukemic infiltrates, lymphocytic																		P		
Hyperplasia, adenomatous, focal							2		2											
Inflammation, chronic-active					1									1			1			1

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	-SDMS Incidence
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL										
Interstitial cell tumor, unilateral/																						
bilateral		P	P	P	P	P	P		P	P	P	P									24/25	23/27
Hyperplasia, interstitial cell, focal,																						
unilateral/bilateral	2				2			1		2	2	2									2/25	9/27
Hypospermatogenesis, multifocal/diffuse,																						
unilateral/bilateral								2				2									0/25	4/27
Germinal cell degeneration, focal/																						
multifocal/diffuse, unilateral/																						
bilateral			3	3	3	2				2	3										4/25	10/27
Tubules, atrophy, compression,																						
focal/multifocal/diffuse,																						
unilateral/bilateral		3					3		3												20/25	15/27
Arteritis, chronic, focal, unilateral/																						
bilateral																					1/25	1/27
PROSTATE	L	L	L	N	L	L	L	L	L	N	L	N										
Leukemic infiltrates, lymphocytic																					0/25	1/27
Hyperplasia, adenomatous, focal																					0/25	2/27
Inflammation, chronic-active	2					1	2	1													6/25	7/27

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PROSTATE (continued)																				
Inflammation, suppurative																2				
Microabscesses																				
EPIDIDYMIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	NN	LL	LL	LL	LL
Leukemic infiltrates, monocytic, bilateral																				
Spermatic granuloma(s), focal, unilateral/bilateral	3																			
Diminution of sperm in ducts, unilateral/bilateral																				
Absence of sperm in ducts, unilateral/bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P			P	P	P	P
Cellular debris in ducts, unilateral/bilateral				P		P	P	P		P	P	P		P			P		P	P
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Inflammation, chronic-active																				

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PROSTATE (continued)																				
Inflammation, suppurative			4												2			3		
Microabscesses																		P		
EPIDIDYMIS	LL	LL	LL	LL	LL	LM	LL	LL	LL	LL	LL	NN	LL	NN	LL	LL	LL	LL	LL	NL
Leukemic infiltrates, monocytic, bilateral																				
Spermatic granuloma(s), focal, unilateral/bilateral																				
Diminution of sperm in ducts, unilateral/bilateral																	2			
Absence of sperm in ducts, unilateral/bilateral	P	P	P	P	P	P	P	P	P	P	P		P		P	P	P	P	P	P
Cellular debris in ducts, unilateral/bilateral	P				P	P	P	P		P					P		P			P
SEMINAL VESICLE	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N
Inflammation, chronic-active									1											

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ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
PROSTATE (continued)																						
Inflammation, suppurative		2	4		1				2		2										2/25	7/27
Microabscesses																					0/25	1/27
EPIDIDYMIS	NN	LL	LL	NN	MM	LL	LL	LL	LL	LL	LL	LL										
Leukemic infiltrates, monocytic,																						
bilateral											P										0/25	1/26
Spermatic granuloma(s), focal,																						
unilateral/bilateral																					1/25	0/26
Diminution of sperm in ducts,																						
unilateral/bilateral		2				2		2	2	3		3									0/25	7/26
Absence of sperm in ducts, unilateral/																						
bilateral		P								P	P										23/25	16/26
Cellular debris in ducts, unilateral/																						
bilateral		P	P			P	P		P	P											13/25	13/26
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N										
Inflammation, chronic-active																					0/25	1/27

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE																		L		
Keratitis, chronic, unilateral/																				
bilateral, focal																		1		
Lens, cataract, unilateral/bilateral																		P		
Degeneration, retinal, unilateral/																				
bilateral																		3		
ADRENAL	L	L	L				L	L			L									L
Pheochromocytoma, unilateral/																				
bilateral			P					P			P									P
Pheochromocytoma, malignant, unilateral	P	P					P													
Leukemic infiltrates, monocytic,																				
unilateral/bilateral	P																			
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral																				
PANCREAS																				
Islet cell carcinoma																				
Hyperplasia, islet cell, focal																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE												N								
Keratitis, chronic, unilateral/																				
bilateral, focal																				
Lens, cataract, unilateral/bilateral																				
Degeneration, retinal, unilateral/																				
bilateral																				
ADRENAL						L			L										L	
Pheochromocytoma, unilateral/																				
bilateral						P														
Pheochromocytoma, malignant, unilateral									P											
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral																			2	
PANCREAS		L																		
Islet cell carcinoma																				
Hyperplasia, islet cell, focal		2																		

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**	TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED														
BY PROTOCOL FOR THIS GROUP														
EYE	N	L												
Keratitis, chronic, unilateral/														
bilateral, focal													1/1	0/3
Lens, cataract, unilateral/bilateral		P											1/1	1/3
Degeneration, retinal, unilateral/														
bilateral													1/1	0/3
ADRENAL	L	L						N			L			
Pheochromocytoma, unilateral/														
bilateral		P											4/7	2/7
Pheochromocytoma, malignant, unilateral													3/7	1/7
Leukemic infiltrates, monocytic,														
unilateral/bilateral													1/7	0/7
Medulla, hyperplasia, focal/multifocal,														
unilateral/bilateral	2										2		0/7	3/7
PANCREAS	N	L	N	N	N						N	N		
Islet cell carcinoma		P											0/1	1/7
Hyperplasia, islet cell, focal													1/1	0/7

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERIC LYMPH NODE									L											
Malignant lymphoma									P											
Monocytic leukemia																				
URINARY BLADDER																				
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																				
LUNG-MAINSTEM BRONCHI	L	L											N				L			
Bronchiolar-alveolar adenoma																	P			
Hemangiosarcoma																				
Carcinoma, metastatic, adrenal	P	P																		
Carcinoma, metastatic, NOS																				
Leukemic infiltrates, lymphocytic		P																		
Leukemic infiltrates, monocytic	P																			
Inflammation, granulomatous, multifocal																				
Microabscesses, focal																				
Fibrinoid degeneration, septae, focal		2																		
ESOPHAGUS																				
TRACHEA																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERIC LYMPH NODE										L	L							L		L
Malignant lymphoma										P								P		P
Monocytic leukemia											P									
URINARY BLADDER																				
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																				
LUNG-MAINSTEM BRONCHI						L		N	N		L				N	L	N		L	
Bronchiolar-alveolar adenoma																				
Hemangiosarcoma																			P	
Carcinoma, metastatic, adrenal																				
Carcinoma, metastatic, NOS						P														
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																P				
Inflammation, granulomatous, multifocal						2														
Microabscesses, focal											P									
Fibrinoid degeneration, septae, focal																				
ESOPHAGUS											N									
TRACHEA											N									

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MESENTERIC LYMPH NODE					N																	
Malignant lymphoma																					1/1	3/5
Monocytic leukemia																					0/1	1/5
URINARY BLADDER			L						N		N											
Cystitis, hemorrhagic-suppurative			4																		-	1/3
Distention, luminal			P																		-	1/3
LUNG-MAINSTEM BRONCHI		N		L			N			L		L										
Bronchiolar-alveolar adenoma																					1/4	0/13
Hemangiosarcoma																					0/4	1/13
Carcinoma, metastatic, adrenal																					2/4	0/13
Carcinoma, metastatic, NOS																					0/4	1/13
Leukemic infiltrates, lymphocytic				P																	1/4	1/13
Leukemic infiltrates, monocytic										P		P									1/4	3/13
Inflammation, granulomatous, multifocal																					0/4	1/13
Microabscesses, focal																					0/4	1/13
Fibrinoid degeneration, septae, focal																					1/4	0/13
ESOPHAGUS											N											
TRACHEA											N											

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYROID								L												
Follicular carcinoma, unilateral																				
Follicular adenoma, unilateral																				
Hyperplasia, C-cell, unilateral/																				
bilateral, focal								1												
STOMACH		N																		
Mucosal erosion(s), glandular region																				
DUODENUM		N																		
JEJUNUM		N																		
ILEUM		N																		
CECUM		L																		
Inflammation		3																		
COLON																				
RECTUM																				
SKIN		L					L	L							N				L	
Malignant fibrous histiocytoma							P													
Dermal fibroma								P											P	
Papilloma																				

continued next page

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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYROID					N	L							L							
Follicular carcinoma, unilateral						P														
Follicular adenoma, unilateral													P							
Hyperplasia, C-cell, unilateral/																				
bilateral, focal																				
STOMACH						L					N									
Mucosal erosion(s), glandular region						3														
DUODENUM															N					
JEJUNUM														I	N					
ILEUM															N					
CECUM											I				N					
Inflammation																				
COLON															N					
RECTUM															N					
SKIN			L					L							L		N			
Malignant fibrous histiocytoma																				
Dermal fibroma			P					P												
Papilloma															P					

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
THYROID								N														
Follicular carcinoma, unilateral																					0/2	1/3
Follicular adenoma, unilateral																					0/2	1/3
Hyperplasia, C-cell, unilateral/																						
bilateral, focal																					1/2	0/3
STOMACH	N										N											
Mucosal erosion(s), glandular region																					0/1	1/4
DUODENUM					N						N											
JEJUNUM					N						N											
ILEUM					N						N											
CECUM	N				N						L											
Inflammation											2										1/1	1/4
COLON					N	N																
RECTUM					N																	
SKIN	N						L		N	N	N											
Malignant fibrous histiocytoma																					1/6	0/8
Dermal fibroma							P														3/6	2/8
Papilloma																					0/6	1/8

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
SKIN (continued)																				
Epidermal ulceration		P																		
Inflammation, dermal, subacute/NOS		P																		
MAMMARY GLAND									L											
Fibroadenoma									P											
Galactoceles																				
STERNUM																				
BONE MARROW																				
Leukemic infiltrates, monocytic																				
ZYMBAL'S GLAND																				
Carcinoma																				
MESENTERY/ABDOMINAL CAVITY				L							L									L
Mesothelioma, (multiple																				
sites)																				
Fibrous histiocytoma (multiple																				
sites																				
Leukemic infiltrates, lymphocytic																				
Lipogranuloma/fat necrosis											P									P

continued next page

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TS = terminal sacrifice SOMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
SKIN (continued)																				
Epidermal ulceration																				
Inflammation, dermal, subacute/NOS																				
MAMMARY GLAND	L		L				L				L									
Fibroadenoma	P						P													
Galactoceles			P								P									
STERNUM																				
BONE MARROW																				
Leukemic infiltrates, monocytic																				
ZYMBAL'S GLAND																L				
Carcinoma																P				
MESENTERY/ABDOMINAL CAVITY			L					L		L	L						L	L	L	
Mesothelioma, (multiple																				
sites)										P										
Fibrous histiocytoma (multiple																				
sites			P																	
Leukemic infiltrates, lymphocytic																		P		
Lipogranuloma/fat necrosis			P					P			P						P	P	P	

continued next page

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**									TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
SKIN (continued)																						
Epidermal ulceration																					1/6	0/8
Inflammation, dermal, subacute/NOS																					1/6	0/8
MAMMARY GLAND	N	L																				
Fibroadenoma		P																			2/3	2/4
Galactoceles																					1/3	1/4
STERNUM											N											
BONE MARROW											L											
Leukemic infiltrates, monocytic											P										-	1/1
ZYMBAL'S GLAND																						
Carcinoma																					-	1/1
MESENTERY/ABDOMINAL CAVITY					L		L		L													
Mesothelioma, (multiple sites)					P																0/4	2/9
Fibrous histiocytoma (multiple sites							P														1/4	1/9
Leukemic infiltrates, lymphocytic																					0/4	1/9
Lipogranuloma/fat necrosis									P												3/4	6/9

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY (continued)																				
Arteritis, chronic				3																
Microabscesses																				
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND													L							L
Carcinoma																				
Adenoma													P							
Inflammation																				P
Inflammatory exudate																				
THYMUS					N															
Monocytic leukemia																				
Atrophy																				
Angiectasis																				
LYMPH NODE(S), NOS									L	L										
Monocytic leukemia										P										
Malignant lymphoma									P											
Lymphoid hyperplasia																				

continued next page

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY (continued)																				
Arteritis, chronic																				
Microabscesses											P									
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND						L														
Carcinoma						P														
Adenoma																				
Inflammation																				
Inflammatory exudate																				
THYMUS						L					L					L			L	
Monocytic leukemia																P				
Atrophy						P					P									
Angiectasis																			P	
LYMPH NODE(S), NOS				L					N	L			L	N		L		L		L
Monocytic leukemia													P			P				
Malignant lymphoma				P						P								P		P
Lymphoid hyperplasia																				

continued next page

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TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MESENTERY/ABDOMINAL CAVITY (continued)																						
Arteritis, chronic																					1/4	0/9
Microabscesses																					0/4	1/9
COAGULATING GLAND				L								L										
Spermatic granuloma(s), focal				1								2									-	2/2
PREPUTIAL GLAND			L																			
Carcinoma																					0/2	1/2
Adenoma																					1/2	0/2
Inflammation																					1/2	0/2
Inflammatory exudate			P																		0/2	1/2
THYMUS					M																	
Monocytic leukemia																					0/1	1/4
Atrophy																					0/1	2/4
Angiectasis																					0/1	1/4
LYMPH NODE(S), NOS			L	L			N				L											
Monocytic leukemia											P										1/3	3/11
Malignant lymphoma				P																	2/3	4/11
Lymphoid hyperplasia											1										0/3	1/11

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Angiectasis																				
SALIVARY GLAND																				
FEMUR/RIB/BONE																				
SUBCUTIS																				
LARYNX																				
MUSCLE																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Angiectasis																				
SALIVARY GLAND																				
FEMUR/RIB/BONE																				
SUBCUTIS															I					
LARYNX																				
MUSCLE																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**	TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED														
BY PROTOCOL FOR THIS GROUP (continued)														
LYMPH NODE(S), NOS (continued)														
Angiectasis			2	3									0/3	2/11
SALIVARY GLAND	N										N			
FEMUR/RIB/BONE	N										N			
SUBCUTIS														
LARYNX											N			
MUSCLE											N			

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
Cerebrum, encephalomalacia, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Myelomalacia, focal																				
Hemorrhage, focal																				
PITUITARY	N	N	L	L	L	L	L	L	N	L	N	L	L	L	L	L	L	L	N	N
Adenoma				P			P	P		P		P		P	P	P	P			
Carcinoma																		P		
Leukemic infiltrates, lymphocytic			P																	
Leukemic infiltrates, monocytic																				
Cyst			P		P	P				P										
Hyperplasia, basophil-cell																				
Hyperplasia, chromophobe-cell													1							

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	L	L	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic													P							
Hemorrhage, focal													3							
Cerebrum, encephalomalacia, focal														2						
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic													P							
Myelomalacia, focal																				
Hemorrhage, focal													2							
PITUITARY	N	L	L	L	L	N	L	L	L	N	N	N	L	L	L	L	N	N	L	L
Adenoma		P	P		P			P					P							P
Carcinoma				P															P	
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic													P	P	P					
Cyst									P											
Hyperplasia, basophil-cell							1									1				
Hyperplasia, chromophobe-cell															1					

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	L	N	N	L	N	N	N	L	N	N	N							
Leukemic infiltrates, lymphocytic												P									0/29	1/26
Leukemic infiltrates, monocytic																					0/29	1/26
Hemorrhage, focal					3							1									0/29	3/26
Cerebrum, encephalomalacia, focal								2													0/29	2/26
SPINAL CORD	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N							
Leukemic infiltrates, monocytic																					0/29	1/26
Myelomalacia, focal			1																		0/29	1/26
Hemorrhage, focal																					0/29	1/26
PITUITARY	N	L	L	L	L	L	L	L	N	L	L	L	N	N	N							
Adenoma				P	P	P	P			P											13/29	7/26
Carcinoma																					2/29	1/26
Leukemic infiltrates, lymphocytic		P						P				P									1/29	3/26
Leukemic infiltrates, monocytic			P			P	P				P										0/29	7/26
Cyst																					5/29	0/26
Hyperplasia, basophil-cell																					1/29	1/26
Hyperplasia, chromophobe-cell								1													1/29	2/26

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Hepatocellular carcinoma																				
Neoplastic nodule																				P
Hemangioma																				
Histiocytic sarcoma																				
Leukemic infiltrates, lymphocytic			P																	
Leukemic infiltrates, monocytic	P					P		P	P	P	P	P						P	P	P
Focus/foci of hyperplasia with cystic degeneration												P								
Area(s) of hyperplasia with cystic degeneration			P							P					P		P	P		P
Foci of cellular alteration-basophilic	P	P		P	P		P	P	P	P	P	P	P	P	P	P	P		P	P
Foci of cellular alteration-eosinophilic				P		P					P		P			P		P	P	
Foci of cellular alteration-clear cells						P														
Area of cellular alteration-clear cells				P	P												P			
Foci of cellular alteration-mixed cells		P						P	P						P					
Necrosis, random, focal																				
Necrosis, liquefaction, focal/multifocal																				
Necrosis, centrilobular, agonal, focal/ multifocal/diffuse																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Hepatocellular carcinoma			P														P			
Neoplastic nodule											P									
Hemangioma																	P			
Histiocytic sarcoma																				
Leukemic infiltrates, lymphocytic																	P			
Leukemic infiltrates, monocytic			P	P	P			P					P	P	P	P				
Focus/foci of hyperplasia with cystic degeneration																				P
Area(s) of hyperplasia with cystic degeneration	P		P			P		P												
Foci of cellular alteration-basophilic	P	P	P	P	P	P		P	P						P					P
Foci of cellular alteration-eosinophilic	P																			
Foci of cellular alteration-clear cells																				
Area of cellular alteration-clear cells		P																		
Foci of cellular alteration-mixed cells		P				P			P											
Necrosis, random, focal																				
Necrosis, liquefaction, focal/multifocal					2															
Necrosis, centrilobular, agonal, focal/ multifocal/diffuse										2										2

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SOMS Incidence
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Hepatocellular carcinoma																					1/29	1/26
Neoplastic nodule																					1/29	1/26
Hemangioma																					0/29	1/26
Histiocytic sarcoma						P															0/29	1/26
Leukemic infiltrates, lymphocytic								P				P									1/29	3/26
Leukemic infiltrates, monocytic			P		P	P	P		P		P		P		P						14/29	12/26
Focus/foci of hyperplasia with cystic degeneration	P																				1/29	2/26
Area(s) of hyperplasia with cystic degeneration																					10/29	0/26
Foci of cellular alteration-basophilic	P	P		P					P	P											25/29	7/26
Foci of cellular alteration-eosinophilic																					8/29	0/26
Foci of cellular alteration-clear cells																					1/29	0/26
Area of cellular alteration-clear cells																					4/29	0/26
Foci of cellular alteration-mixed cells																					7/29	0/26
Necrosis, random, focal					2																0/29	1/26
Necrosis, liquefaction, focal/multifocal																					1/29	0/26
Necrosis, centrilobular, agonal, focal/multifocal/diffuse	1	1												2	2						0/29	6/26

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
TS = terminal sacrifice SOMS = spontaneous death/moribund sacrifice

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
LIVER (continued)																				
Bile duct proliferation, focal/																				
multifocal/diffuse	2	2	3	2	2	2	2	3	3	3	2	3	2	2	2	2	2	2	2	3
Cholangiofibrosis, focal/multifocal	2	2	3			2		2	2	2	2	2	2	2	2		2	2		2
Metamorphosis, fatty, centrilobular/																				
periportal/random, focal/																				
multifocal/diffuse								3												
Extramedullary hematopoiesis, focal/																				
multifocal																				
Cyst, parenchymal																				
Hematocyst																				
Microgranulomas, focal/multifocal																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral			P																	
Leukemic infiltrates, monocytic,																				
bilateral											P									
Nephropathy, chronic, bilateral	2	3	3	2	2	2	3	3	2	3	2	2	3	2	2	3	2	3	2	3
Inflammation, lymphocytic, bilateral	1	2	1	1	1	1	2	2	1	2	1	1	2	2	1	2	2	2	2	2

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terminal sac — SDMS spontaneous death/moribund sacrifice

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ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
LIVER (continued)																				
Bile duct proliferation, focal/																				
multifocal/diffuse	3	2		2	3	2	1	2	2	2	2	2	3	3	2	2	3	2	2	2
Cholangiofibrosis, focal/multifocal	2	2		2	2		1	2	2				3	2	2	1	2			1
Metamorphosis, fatty, centrilobular/																				
periportal/random, focal/																				
multifocal/diffuse																				
Extramedullary hematopoiesis, focal/																				
multifocal											1									
Cyst, parenchymal																				
Hematocyst																				
Microgranulomas, focal/multifocal																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
bilateral													P		P					
Nephropathy, chronic, bilateral	3	3	3	4	3	3	2	2	3	2	3	2	3	3	2	2	2	3	2	2
Inflammation, lymphocytic, bilateral	2	2	1	2	2	2	1	1	2	1			1	1		1		1	1	

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LIVER (continued)																						
Bile duct proliferation, focal/																						
multifocal/diffuse	2	2	2	2	2	2	2	2	2	2	3	2	3	2	3						28/29	26/26
Cholangiofibrosis, focal/multifocal	2	2			2			3	2		2	2	3		2						22/29	15/26
Metamorphosis, fatty, centrilobular/																						
periportal/random, focal/																						
multifocal/diffuse				3								2									1/29	2/26
Extramedullary hematopoiesis, focal/																						
multifocal																					0/29	1/26
Cyst, parenchymal														P							0/29	1/26
Hematocyst	P																				0/29	1/26
Microgranulomas, focal/multifocal				1																	0/29	1/26
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL							
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral												P									1/29	1/26
Leukemic infiltrates, monocytic,																						
bilateral						P			P												1/29	4/26
Nephropathy, chronic, bilateral	2	2	2	3	3	2	2	3	2	2	2	2	2	3	2						29/29	26/26
Inflammation, lymphocytic, bilateral	1	1	1	2	1	1	1	2	1					1							29/29	16/26

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
KIDNEY (continued)																				
Microconcretions, tubular, unilateral/																				
bilateral																				
Pyelonephritis, unilateral/bilateral														1						
Pyelitis, suppurative, unilateral/																				
bilateral																				
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets,																				
bilateral			2									2								
Cyst, cortical, unilateral													P					P		
HEART	L	L	N	L	L	L	L	L	L	L	L	N	L	L	L	L	L	L	L	L
Endocardial neurolemmoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1		1	2	2	1	2	1	2	1		2	1	1	2	2	1	1	2
Auricular thrombosis																				
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Malignant lymphoma			P																	

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ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
KIDNEY (continued)																				
Microconcretions, tubular, unilateral/ bilateral																				1
Pyelonephritis, unilateral/bilateral																				
Pyelitis, suppurative, unilateral/ bilateral															1					
Cortex, increased pigment, bilateral											2				2		2			
Cortex, protein resorption droplets, bilateral										3				2						
Cyst, cortical, unilateral																				
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N
Endocardial neurolemmoma																				
Leukemic infiltrates, lymphocytic																	P			
Leukemic infiltrates, monocytic													P	P	P					
Myocarditis, chronic, focal/multifocal	2	1	1	2	1	2	2	1	2	2	2	1		2	2	2		1	1	
Auricular thrombosis																				
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Malignant lymphoma																	P			

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
KIDNEY (continued)																						
Microconcretions, tubular, unilateral/																						
bilateral																					0/29	1/26
Pyelonephritis, unilateral/bilateral									2												1/29	1/26
Pyelitis, suppurative, unilateral/																						
bilateral																					0/29	1/26
Cortex, increased pigment, bilateral									2												0/29	4/26
Cortex, protein resorption droplets,																						
bilateral				2																	2/29	3/26
Cyst, cortical, unilateral																					2/29	0/26
HEART	L	L	L	N	N	L	L	L	L	L	L	L	N	L	L							
Endocardial neurolemmoma	P																				0/29	1/26
Leukemic infiltrates, lymphocytic		P										P									0/29	3/26
Leukemic infiltrates, monocytic			P																		0/29	4/26
Myocarditis, chronic, focal/multifocal		2				1	1	2	1	2	1	2		2	1						27/29	18/26
Auricular thrombosis	P							P													0/29	2/26
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Malignant lymphoma		P						P				P									1/29	4/26

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ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
SPLEEN (continued)																				
Monocytic leukemia	P					P		P	P	P	P	P						P	P	P
Congestion, diffuse		1											2							
Fibrosis, focal															3					
Increased extramedullary hematopoiesis														1						
Increased pigment, diffuse				1	2		2							1	2	1	2			
Infarction, focal/multifocal																				
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Interstitial cell tumor, unilateral/ bilateral	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P		P	P	P
Hyperplasia, interstitial cell, focal, unilateral/bilateral				2																
Hypospermatogenesis, multifocal/diffuse, unilateral/bilateral																				
Germinal cell degeneration, focal/ multifocal/diffuse, unilateral/ bilateral				3	3							3				3			3	

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F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
SPLEEN (continued)																				
Monocytic leukemia			P	P	P			P					P	P	P	P				
Congestion, diffuse		2																2		
Fibrosis, focal																				
Increased extramedullary hematopoiesis										3	3	2				2				2
Increased pigment, diffuse	1					1	1		2									2	2	
Infarction, focal/multifocal											3			2						
TESTIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL
Interstitial cell tumor, unilateral/ bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P
Hyperplasia, interstitial cell, focal, unilateral/bilateral																2				
Hypospermatogenesis, multifocal/diffuse, unilateral/bilateral																				
Germinal cell degeneration, focal/ multifocal/diffuse, unilateral/ bilateral	3						3										3			3

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
TS = terminal sacrifice SDMS - spontaneous death/moribund sacrifice

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ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
SPLEEN (continued)																						
Monocytic leukemia			P		P	P	P		P		P		P		P						14/29	12/26
Congestion, diffuse										2											3/29	2/26
Fibrosis, focal	2								2												1/29	2/26
Increased extramedullary hematopoiesis				1			2							1							1/29	8/26
Increased pigment, diffuse				2						1											11/29	4/26
Infarction, focal/multifocal																					0/29	2/26
TESTIS	LL	LL	LL	NL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL							
Interstitial cell tumor, unilateral/																						
bilateral	P	P	P		P	P	P	P	P	P	P	P	P	P	P						27/29	24/26
Hyperplasia, interstitial cell, focal,																						
unilateral/bilateral																					1/29	1/26
Hypospermatogenesis, multifocal/diffuse,																						
unilateral/bilateral											3				3						0/29	2/26
Germinal cell degeneration, focal/																						
multifocal/diffuse, unilateral/																						
bilateral		3		3						2			3								7/29	6/26

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ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
TESTIS (continued)																				
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3	3	3	3	3	3	3	3	3	3		3	3	3	3		3	3	3
Arteritis, chronic, focal, unilateral/																				
bilateral																	1			
PROSTATE	N	N	L	L	N	N	N	N	N	L	N	L	L	N	L	L	L	N	N	N
Leukemic infiltrates, lymphocytic																				
Inflammation, chronic-active			1	1						1			2							
Inflammation, suppurative												3			1	3	3			
Cysts																				
EPIDIDYMIS	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	NN	LL	LL	LL
Leukemic infiltrates, monocytic																				
Diminution of sperm in ducts,																				
unilateral/bilateral													2	3					3	
Absence of sperm in ducts, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P	P	P			P	P	P		P	P	P

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TESTIS (continued)																				
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3	3	3	3	3		3	3	3	3	3	3	3	3			3		3
Arteritis, chronic, focal, unilateral/																				
bilateral																				
PROSTATE	N	N	L	L	N	N	N	N	N	L	L	N	L	L	L	N	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Inflammation, chronic-active			1	1						1			1					1		1
Inflammation, suppurative														1	2		1		2	
Cysts											P									
EPIDIDYMIS	LL	LL	LL	LL	LL	LL	LL	NL	LL	LL	LL	NL	LL	LL	LL	NN	LL	LL	NN	LL
Leukemic infiltrates, monocytic																				
Diminution of sperm in ducts,																				
unilateral/bilateral																		2		
Absence of sperm in ducts, unilateral/																				
bilateral	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P		P

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TESTIS (continued)																						
Tubules, atrophy, compression,																						
focal/multifocal/diffuse,																						
unilateral/bilateral	3	3	3		3	3	3	3	3	3	3	3	3	3	3						26/29	22/26
Arteritis, chronic, focal, unilateral/																						
bilateral																					1/29	0/26
PROSTATE	N	N	N	L	N	L	L	L	N	N	L	N	L	N	N							
Leukemic infiltrates, lymphocytic								P													0/29	1/26
Inflammation, chronic-active							1														6/29	5/26
Inflammation, suppurative				3		2					1		3								4/29	8/26
Cysts																					0/29	1/26
EPIDIDYMIS	LL	LL	LL	NN	LL	LL	NN	LL	LL	LL	LL	LL	LL	LL	LL							
Leukemic infiltrates, monocytic									P												0/29	1/26
Diminution of sperm in ducts,																						
unilateral/bilateral		3								2											3/29	3/26
Absence of sperm in ducts, unilateral/																						
bilateral	P	P	P		P	P		P	P	P	P	P	P	P	P						26/29	22/26

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EPIDIDYMIS (continued)																				
Cellular debris in ducts, unilateral/																				
bilateral	P	P		P		P	P	P	P	P	P		P	P	P	P		P	P	P
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Inflammation, chronic-active																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE															L					
Keratitis with ulceration																				
Lens, cataract, unilateral															P					
Degeneration, retinal, unilateral/																				
bilateral																				
ADRENAL			L								L	L								
Pheochromocytoma,																				
unilateral/bilateral											P	P								
Pheochromocytoma, malignant, unilateral																				

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EPIDIDYMIS (continued)																				
Cellular debris in ducts, unilateral/																				
bilateral	P	P			P	P	P	P	P			P	P		P			P		
SEMINAL VESICLE	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Inflammation, chronic-active				2																
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE							L									L				
Keratitis with ulceration																				
Lens, cataract, unilateral							P									P				
Degeneration, retinal, unilateral/																				
bilateral							4													
ADRENAL	L	L		L							L	L								
Pheochromocytoma,																				
unilateral/bilateral		P									P									
Pheochromocytoma, malignant, unilatera	P			P																

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EPIDIDYMIS (continued)																						
Cellular debris in ducts, unilateral/																						
bilateral			P		P			P		P	P	P	P	P							23/29	12/26
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N							
Inflammation, chronic-active																					1/29	0/26
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP																						
EYE				NN		L																
Keratitis with ulceration						3															0/2	1/3
Lens, cataract, unilateral																					2/2	1/3
Degeneration, retinal, unilateral/																						
bilateral																					1/2	0/3
ADRENAL		L				L								L								
Pheochromocytoma,																						
unilateral/bilateral						P								P							3/6	3/5
Pheochromocytoma, malignant, unilateral																					2/6	0/5

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL (continued)																				
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral			P																	
Leukemic infiltrates, monocytic,																				
unilateral/bilateral												P								
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral			1																	
Extamedullary hematopoiesis, focal/																				
multifocal, unilateral/bilateral																				
PANCREAS																				
Leukemic infiltrates, monocytic																				
MESENTERIC LYMPH NODE																				
Malignant lymphoma																				
Monocytic leukemia																				
Angiectasis																				
Extramedullary hematopoiesis																				
URINARY BLADDER						N								L						
Cystitis, suppurative														2						

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL (continued)																				
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral												2								
Extamedullary hematopoiesis, focal/																				
multifocal, unilateral/bilateral											2									
PANCREAS					N								L							
Leukemic infiltrates, monocytic													P							
MESENTERIC LYMPH NODE													L				L			
Malignant lymphoma																				
Monocytic leukemia													P							
Angiectasis																				
Extramedullary hematopoiesis																	1			
URINARY BLADDER													M							
Cystitis, suppurative																				

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TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
ADRENAL (continued)																						
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral		P																			1/6	1/5
Leukemic infiltrates, monocytic,																						
unilateral/bilateral						P															1/6	1/5
Medulla, hyperplasia, focal/multifocal,																						
unilateral/bilateral																					1/6	1/5
Extamedullary hematopoiesis, focal/																						
multifocal, unilateral/bilateral																					0/6	1/5
PANCREAS																						
Leukemic infiltrates, monocytic																					0/1	1/1
MESENTERIC LYMPH NODE	L		L					L			L		N									
Malignant lymphoma								P													-	1/6
Monocytic leukemia			P																		-	2/6
Angiectasis	2										3										-	2/6
Extramedullary hematopoiesis																					-	1/6
URINARY BLADDER			N									L		L	L							
Cystitis, suppurative																					1/2	0/4

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
URINARY BLADDER (continued)																				
Distention, luminal																				
LUNG-MAINSTEM BRONCHI								L				L								L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic								P				P								P
Carcinoma, metastatic, adrenal																				
Sarcoma, metastatic																				
Alveolar macrophages, focal/multifocal																				
Fibrinoid degeneration, septae, focal																				
THYROID								L												
C-cell adenoma, unilateral								P												
Follicular cystadenocarcinoma																				
STOMACH																				
Mucosal ulcer(s), glandular region																				
Mucosal erosion(s), glandular region																				
RECTUM																				
SKIN	L									L				L					L	
Dermal fibroma	P									P										

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
URINARY BLADDER (continued)																				
Distention, luminal																				
LUNG-MAINSTEM BRONCHI				L	L								L		L		L			L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic					P								P		P					
Carcinoma, metastatic, adrenal				P													P			
Sarcoma, metastatic					P															
Alveolar macrophages, focal/multifocal																				1
Fibrinoid degeneration, septae, focal																				1
THYROID							L													
C-cell adenoma, unilateral																				
Follicular cystadenocarcinoma							P													
STOMACH													L							
Mucosal ulcer(s), glandular region																				
Mucosal erosion(s), glandular region													3							
RECTUM																				
SKIN					L					L			L			L			N	L
Dermal fibroma																P				

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TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
URINARY BLADDER (continued)																						
Distention, luminal												P		P	P						0/2	3/4
LUNG-MAINSTEM BRONCHI		L	L		L			L				L	L		L							
Leukemic infiltrates, lymphocytic		P						P				P									0/5	3/11
Leukemic infiltrates, monocytic			P		P								P		P						4/5	6/11
Carcinoma, metastatic, adrenal																					1/5	1/11
Sarcoma, metastatic																					1/5	0/11
Alveolar macrophages, focal/multifocal																					0/5	1/11
Fibrinoid degeneration, septae, focal																					0/5	1/11
THYROID																						
C-cell adenoma, unilateral																					1/2	-
Follicular cystadenocarcinoma																					1/2	-
STOMACH			L		L			L		L			L									
Mucosal ulcer(s), glandular region			3							3			3								-	3/6
Mucosal erosion(s), glandular region					3			3		3											-	4/6
RECTUM		N	N																			
SKIN	L				N	L				L	N		L									
Dermal fibroma						P				P											2/5	3/11

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
SKIN (continued)																				
Dermal fibrosarcoma																				
Keratoacanthoma																				
Epidermal inclusion cyst																			P	
Epidermal ulceration																				
Acanthosis														1						
Dermal hemangioma																				
MAMMARY GLAND																	L			
Fibroadenoma																				
Galactoceles																	P			
Inflammation																	2			
BONE MARROW																				
Leukemic infiltrates, monocytic																				
MESENTERY/ABDOMINAL CAVITY			L			L					L				L	L	L			
Mesothelioma, (multiple																				
sites)																				
Fibrous histiocytoma (multiple																				
sites)																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
SKIN (continued)																				
Dermal fibrosarcoma																				
Keratoacanthoma													P							P
Epidermal inclusion cyst					P					P										
Epidermal ulceration																				
Acanthosis																				
Dermal hemangioma																				
MAMMARY GLAND						L														
Fibroadenoma						P														
Galactoceles																				
Inflammation																				
BONE MARROW													L							
Leukemic infiltrates, monocytic													P							
MESENTERY/ABDOMINAL CAVITY				L				L		L	L	L								
Mesothelioma, (multiple																				
sites)										P										
Fibrous histiocytoma (multiple																				
sites)												P								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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continued next page

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
SKIN (continued)																						
Dermal fibrosarcoma						P															0/5	1/11
Keratoacanthoma																					0/5	2/11
Epidermal inclusion cyst	P					P															2/5	3/11
Epidermal ulceration													P								0/5	1/11
Acanthosis																					1/5	0/11
Dermal hemangioma	P																				0/5	1/11
MAMMARY GLAND				L																		
Fibroadenoma																					1/2	0/1
Galactoceles				P																	1/2	1/1
Inflammation																					1/2	0/1
BONE MARROW			L																			
Leukemic infiltrates, monocytic			P																		-	2/2
MESENTERY/ABDOMINAL CAVITY		L	L	L			L			L		L			L							
Mesothelioma, (multiple sites)																					0/8	1/10
Fibrous histiocytoma (multiple sites)																					0/8	1/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY (continued)																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Lipogranuloma/fat necrosis			P			P					P				P	P	P			
COAGULATING GLAND																				
Spermatic granuloma(s), focal																				
PREPUTIAL GLAND			L						L		L	L							L	
Adenoma			P						P		P								P	
Inflammation																				
Abscess																				
Cysts												P								
THYMUS																				
Malignant lymphoma																				
Atrophy																				
LYMPH NODE(S), NOS			L									L								
Monocytic leukemia												P								
Malignant lymphoma			P																	
Carcinoma, metastatic, adrenal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MESENTERY/ABDOMINAL CAVITY (continued)																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Lipogranuloma/fat necrosis				P				P			P									
COAGULATING GLAND													L							
Spermatic granuloma(s), focal													2							
PREPUTIAL GLAND																		L		
Adenoma																		P		
Inflammation																				
Abscess																				
Cysts																				
THYMUS																	L			
Malignant lymphoma																				
Atrophy																	P			
LYMPH NODE(S), NOS		L	L										L				L			
Monocytic leukemia													P							
Malignant lymphoma																				
Carcinoma, metastatic, adrenal																	P			

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MESENTERY/ABDOMINAL CAVITY (continued)																						
Leukemic infiltrates, lymphocytic		P																			0/8	1/10
Leukemic infiltrates, monocytic			P																		0/8	1/10
Lipogranuloma/fat necrosis		P	P	P			P			P		P			P						8/8	8/10
COAGULATING GLAND			L																			
Spermatic granuloma(s), focal			2																		-	2/2
PREPUTIAL GLAND		L					L															
Adenoma																					4/5	1/3
Inflammation							P														0/5	1/3
Abscess		P																			0/5	1/3
Cysts																					1/5	0/3
THYMUS		L	M					L														
Malignant lymphoma		P						P													-	2/3
Atrophy																					-	1/3
LYMPH NODE(S), NOS	L	L	L					L			L	L										
Monocytic leukemia			P								P										1/4	3/8
Malignant lymphoma		P						P				P									1/4	3/8
Carcinoma, metastatic, adrenal																					0/4	1/8

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present
2 = mild 4 = severe L = lesion present I = tissue section inadequate
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
* = moribund sacrifice
** = spontaneous death

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F344 Male Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Lymphoid hyperplasia																				
Angiectasis																				
SALIVARY GLAND																				
Histiocytic sarcoma																				
PROSTATIC URETHRAL GLAND																				
Hemangioma																				
FEMUR																				

continued
next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6966*	80-6972*	80-6974*	80-6977*	80-6982*	80-6984*	80-7000*	80-7001*	80-7002*	80-7005*	80-7010*
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LYMPH NODE(S), NOS (continued)																				
Lymphoid hyperplasia		1	1																	
Angiectasis																				
SALIVARY GLAND																				
Histiocytic sarcoma																				
PROSTATIC URETHRAL GLAND																				
Hemangioma																				
FEMUR													N							

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7012*	80-7013*	80-7020*	80-7024*	80-7028*	80-6961**	80-6965**	80-6970**	80-6979**	80-6981**	80-6985**	80-6990**	80-7021**	80-7025**	80-7026**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
LYMPH NODE(S), NOS (continued)																						
Lymphoid hyperplasia																					2/4	0/8
Angiectasis	2										3										0/4	2/8
SALIVARY GLAND			L																			
Histiocytic sarcoma			P																		-	1/1
PROSTATIC URETHRAL GLAND	L																					
Hemangioma	P																				-	1/1
FEMUR			N																			

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F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7127	80-7141	80-7156	80-7174	80-7109*	80-7113*	80-7117*	80-7124*	80-7130*	80-7140*	80-7144*	80-7146*	80-7154*	80-7160*	80-7161*	80-7162*	80-7169*	80-7118**	80-7125**	80-7131**
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	L	N	L	N	N	N	N	N
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic													P							
Hemorrhage, focal													3							
Bacteremia																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	L	N	L	N	N	N	N	N
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic													P							
PITUITARY	N	N	N	N	N	N	N	L	L	L	L	L	L	N	L	L	N	N	N	N
Adenoma											P				P					
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic													P							
Cyst								P		P						P				
Hyperplasia, basophil-cell									1			1								
Hyperplasia, chromophobe-cell																1				
EYE	NL	LM	NL	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NL	NN	NN	NN	NN	NL
Lens, cataract, unilateral/bilateral		P	P		P															P

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FINAL REPORT
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	TS Incidence	SOMS Incidence
BRAIN	L	N	N	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic												0/4	1/27
Hemorrhage, focal	2											0/4	2/27
Bacteremia	P											0/4	1/27
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic												0/4	1/27
PITUITARY	L	N	N	N	L	L	L	L	N	L	N		
Adenoma						P						0/4	3/27
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic	P							P		P		0/4	4/27
Cyst												0/4	3/27
Hyperplasia, basophil-cell												0/4	2/27
Hyperplasia, chromophobe-cell					2		1					0/4	3/27
EYE	NN	LL	NN	NN	NN	LL	NL	NN	NN	NN	NN		
Lens, cataract, unilateral/bilateral		P										2/4	3/27

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ORGAN Lesion / Accession Number	80-7127	80-7141	80-7156	80-7174	80-7109*	80-7113*	80-7117*	80-7124*	80-7130*	80-7140*	80-7144*	80-7146*	80-7154*	80-7160*	80-7161*	80-7162*	80-7169*	80-7118**	80-7125**	80-7131**
EYE (continued																				
Lens-induced inflammation, unilateral															P					
Degeneration, retinal, unilateral/																				
bilateral	3																			
Retinal dysplasia, unilateral					3															3
OPTIC NERVE	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
ADRENAL	NL	NL	LL	LL	NN	LL	NN	NN	NN	NN	NN	NN	LL	NN	LL	NN	NN	NL	NN	NN
Pheochromocytoma, unilateral/bilateral				P														P		
Leukemic infiltrates, monocytic,																				
unilateral/bilateral			P	P									P							
Cortex, metamorphosis, fatty, unilateral/																				
bilateral		2		1									1		1					
Cortex, angiectasis, unilateral/																				
bilateral, focal						2														
Medulla, hyperplasia, focal/multifocal,																				
unilateral/bilateral	2	1													2					

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	IS Incidence	SDMS Incidence
EYE (continued													
Lens-induced inflammation, unilateral		P					P					0/4	3/27
Degeneration, retinal, unilateral/													
bilateral		3				3						1/4	2/27
Retinal dysplasia, unilateral												0/4	2/27
OPTIC NERVE	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN		
ADRENAL	LL	NN	LL	NN	NL	NN	NL	NN	NN	LL	NN		
Pheochromocytoma, unilateral/bilateral	P				P							1/4	3/27
Leukemic infiltrates, monocytic,													
unilateral/bilateral	P									P		2/4	3/27
Cortex, metamorphosis, fatty, unilateral/													
bilateral			1				1					2/4	4/27
Cortex, angiectasis, unilateral/													
bilateral, focal												0/4	1/27
Medulla, hyperplasia, focal/multifocal,													
unilateral/bilateral										2		2/4	2/27

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7127	80-7141	80-7156	80-7174	80-7109*	80-7113*	80-7117*	80-7124*	80-7130*	80-7140*	80-7144*	80-7146*	80-7154*	80-7160*	80-7161*	80-7162*	80-7169*	80-7118**	80-7125**	80-7131**
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L
Malignant lymphoma															P					
Monocytic leukemia	P	P	P	P									P							
Increased pigment, diffuse					2	2	2	3	2	2	2	3		2		2	2	2		2
PANCREAS	N	N	N	L	N	L	N	N	N	N	N	N	L	N	N	L	N	N	L	N
Islet cell adenoma																			P	
Leukemic infiltrates, monocytic													P							
Hyperplasia, islet cell, focal																				
Atrophy, acinar cell, focal				3		2										2			2	
MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	N	N	N	N	L	N	L	N	N	N	N	N
Monocytic leukemia													P							
Malignant lymphoma															P					
TESTIS	LL	LL	LL	LL	LL	NN	NN	NN	NN	NN	NN	NN	LL	NN	LL	NL	NN	LL	LL	NN
Capsule/NOS, mesothelioma, unilateral/																				
bilateral																		P		
Interstitial cell tumor, unilateral/																				
bilateral	P	P	P	P									P		P	P			P	

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	TS Incidence	SDMS Incidence
SPLEEN	L	L	L	L	N	N	L	L	L	L	L		
Malignant lymphoma												0/4	1/27
Monocytic leukemia	P							P	P	P		4/4	5/27
Increased pigment, diffuse		2	2	1			2				2	0/4	18/27
PANCREAS	N	N	N	N	N	L	N	N	L	L	N		
Islet cell adenoma									P			0/4	2/27
Leukemic infiltrates, monocytic												0/4	1/27
Hyperplasia, islet cell, focal						3				2		0/4	2/27
Atrophy, acinar cell, focal										2		1/4	4/27
MESENTERIC LYMPH NODE	L	N	N	N	N	N	N	M	N	L	N		
Monocytic leukemia	P									P		0/4	3/26
Malignant lymphoma												0/4	1/26
TESTIS	NN	NL	NL	NL	LL	LL	NL	LL	LL	LL	NL		
Capsule/NOS, mesothelioma, unilateral/													
bilateral						P		P				0/4	3/27
Interstitial cell tumor, unilateral/													
bilateral		P	P	P	P	P	P		P	P		4/4	12/27

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TESTIS (continued)																				
Hyperplasia, interstitial cell, focal,																				
unilateral/bilateral					2															
Germinal cell degeneration, focal/																				
multifocal/diffuse, unilateral/																				
bilateral	3												3		2					
Tubules, atrophy, compression,																				
focal/multifocal/diffuse,																				
unilateral/bilateral	3	3	3	3									3							
PROSTATE	N	L	N	L	L	L	L	L	L	N	L	L	N	L	N	L	L	L	L	L
Hyperplasia, adenomatous, focal				2																
Inflammation, chronic-active		1																		
Inflammation, suppurative					4	2	2	3	2		2	3		1		3	4	4	4	2
Microabscesses																			P	
EPIDIDYMIS	LL	LL	LL	NL	NN	NN	NN	NN	NN	LL	NN	NN	LL	NN	LL	NN	NN	NL	LL	NN
Capsule, mesothelioma, unilateral/																				
bilateral																		P		

continued next page

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ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**										TS Incidence	SDMS Incidence
TESTIS (continued)																						
Hyperplasia, interstitial cell, focal,																						
unilateral/bilateral											2										0/4	2/27
Germinal cell degeneration, focal/																						
multifocal/diffuse, unilateral/																						
bilateral										3											1/4	3/27
Tubules, atrophy, compression,																						
focal/multifocal/diffuse,																						
unilateral/bilateral			3	3	3				3	3											4/4	6/27
PROSTATE	N	L	L	L	N	L	N	N	L	L	L											
Hyperplasia, adenomatous, focal																					1/4	0/27
Inflammation, chronic-active		1																			1/4	1/27
Inflammation, suppurative			3	3		3			3	2	3										0/4	19/27
Microabscesses																					0/4	1/27
EPIDIDYMIS	NN	NN	NL	NL	LL	NN	LL	NN	LL	LL	NN											
Capsule, mesothelioma, unilateral/																						
bilateral																					0/4	1/27

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7127	80-7141	80-7156	80-7174	80-7109*	80-7113*	80-7117*	80-7124*	80-7130*	80-7140*	80-7144*	80-7146*	80-7154*	80-7160*	80-7161*	80-7162*	80-7169*	80-7118**	80-7125**	80-7131**
EPIDIDYMIS (continued)																				
Spermatic granuloma(s), focal,																				
unilateral/bilateral				3									3							
Diminution of sperm in ducts,																				
unilateral/bilateral				2															2	
Absence of sperm in ducts, unilateral/																				
bilateral	P	P	P										P		P					
Cellular debris in ducts, unilateral/																				
bilateral		P		P						P			P		P				P	
SEMINAL VESICLE	N	N	L	N	L	L	L	L	L	N	L	L	N	L	N	L	L	L	L	L
Inflammation, suppurative						1						1					1	2		
Distended with secretion			P		P	P	P	P	P		P	P		P		P		P	P	P
URINARY BLADDER	N	N	N	L	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic													P							
Cystitis, hemorrhagic-suppurative					4	3	2	2	4		3	4		1		4	3	4	4	3
Cystitis, hemorrhagic																				
Mineralization, uremic																			1	

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ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	TS Incidence	SDMS Incidence
EPIDIDYMIS (continued)													
Spermatic granuloma(s), focal, unilateral/bilateral												1/4	1/27
Diminution of sperm in ducts, unilateral/bilateral			2	2			2					1/4	4/27
Absence of sperm in ducts, unilateral/bilateral					P				P	P		3/4	5/27
Cellular debris in ducts, unilateral/bilateral			P	P			P		P	P		2/4	9/27
SEMINAL VESICLE	N	L	L	L	N	L	N	N	L	L	L		
Inflammation, suppurative			1	1		2					2	0/4	8/27
Distended with secretion		P		P		P			P	P	P	1/4	18/27
URINARY BLADDER	L	L	L	L	L	L	N	L	L	L	L		
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic	P											0/4	2/27
Cystitis, hemorrhagic-suppurative			3	3		3					4	0/4	17/27
Cystitis, hemorrhagic		2										0/4	1/27
Mineralization, uremic												0/4	1/27

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URINARY BLADDER (continued)																				
Distention, luminal				P	P	P	P	P	P		P	P		P	P	P	P	P	P	P
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Bronchiolar-alveolar adenoma								P												
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic			P	P									P							
Alveolar macrophages, focal/multifocal/ diffuse				2						2			2		2				1	
Lymphoid infiltrates, peribronchial/iolar, focal	2	1	2	1	1	1	1	2	2	1	1	2	2	1	2	1	1	1		1
Hemorrhage, focal/multifocal						2														
Congestion, agonal, diffuse						3	2				2						2	2		
Mineralization, alveolar, uremic																	1			
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	L	L	L	L	N	N	N	N	N	N	N	L	N	N	L	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Inflammation, chronic	2	2	2	2								1			1					

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URINARY BLADDER (continued)													
Distention, luminal		P	P	P	P	P		P	P	P	P	1/4	23/27
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L		
Bronchiolar-alveolar adenoma												0/4	1/27
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic	P							P	P	P		2/4	5/27
Alveolar macrophages, focal/multifocal/													
diffuse								3		2		1/4	6/27
Lymphoid infiltrates,													
peribronchial/iolar, focal	2	2	2	1	2	1	1	2	1	1	2	4/4	26/27
Hemorrhage, focal/multifocal								3				0/4	2/27
Congestion, agonal, diffuse												0/4	5/27
Mineralization, alveolar, uremic												0/4	1/27
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N		
TRACHEA	L	L	N	N	N	N	N	L	N	L	N		
Leukemic infiltrates, monocytic										P		0/4	1/27
Inflammation, chronic	1	1						1				4/4	5/27

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THYROID	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NL	NL	NN	NL	NL	NN
C-cell adenoma, unilateral		P																P	P	
Follicular cystadenoma, unilateral/																				
bilateral																P				
Cystic follicle(s), unilateral/bilateral		P													P					
PARATHYROID	NL	NM	NN	NN	NN	NN	NN	NN	NN	NN	LL	LL	NM	LL	LM	NN	LL	NN	LM	NN
Hyperplasia, unilateral/bilateral	3										1	1		1	2		1		3	
HEART	L	L	L	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic			P										P							
Myocarditis, chronic, focal/multifocal	2	2	1	2	1	1	1	2		2	1	1	1	1		2		1	2	2
Auricular thrombosis																				
Mineralization, vessels, uremic						1						1		3		2	3			
Mineralization, myocardial, uremic														2			2			
Vegetative endocarditis																				
Bacteremia																				

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THYROID	NL	NN	NN	NN	LL	NN	NN	LL	NN	NN	NN		
C-cell adenoma, unilateral												1/4	2/27
Follicular cystadenoma, unilateral/ bilateral												0/4	1/27
Cystic follicle(s), unilateral/bilateral	P				P			P				1/4	4/27
PARATHYROID	LM	LL	NN	NM	NL	LL	NM	NM	NM	NN	LL		
Hyperplasia, unilateral/bilateral	2	1			1	2					1	1/4	11/27
HEART	L	L	L	L	L	L	L	L	L	L	L		
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic	P											1/4	2/27
Myocarditis, chronic, focal/multifocal		2	1	1	2	1	1	2	1	1		4/4	22/27
Auricular thrombosis									P	P		0/4	2/27
Mineralization, vessels, uremic											2	0/4	6/27
Mineralization, myocardial, uremic												0/4	2/27
Vegetative endocarditis	P											0/4	1/27
Bacteremia	P											0/4	1/27

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LIVER	L	L	L	L	L	L	L	L	N	L	N	N	L	L	L	L	N	N	L	L
Hepatocellular carcinoma																				P
Neoplastic nodule	P																			
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic		P	P	P									P							
Area(s) of hyperplasia with cystic degeneration				P						P										
Foci of cellular alteration-basophilic	P		P	P																
Foci of cellular alteration-eosinophilic	P		P	P																
Foci of cellular alteration-mixed cells																				
Necrosis, random, focal		2																		
Necrosis, liquefaction, focal/multifocal																1				
Necrosis, centrilobular, agonal, focal/multifocal/diffuse														3						
Bile duct proliferation, focal/multifocal/diffuse	2	2	1	2	1	1		1		2			3		2				2	
Cholangiofibrosis, focal/multifocal		2	1			1	1			2			2						2	

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LIVER	L	L	N	L	L	L	L	L	L	L	L		
Hepatocellular carcinoma	P											0/4	2/27
Neoplastic nodule												1/4	0/27
Leukemic infiltrates, lymphocytic												0/4	1/27
Leukemic infiltrates, monocytic	P							P	P	P		3/4	5/27
Area(s) of hyperplasia with cystic degeneration												1/4	1/27
Foci of cellular alteration-basophilic									P			3/4	1/27
Foci of cellular alteration-eosinophilic												3/4	0/27
Foci of cellular alteration-mixed cells		P		P								0/4	2/27
Necrosis, random, focal												1/4	0/27
Necrosis, liquefaction, focal/multifocal												0/4	1/27
Necrosis, centrilobular, agonal, focal/multifocal/diffuse									1			0/4	2/27
Bile duct proliferation, focal/ multifocal/diffuse	2				2	2	1	2	3	2	1	4/4	15/27
Cholangiofibrosis, focal/multifocal						2			2	2		2/4	8/27

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KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Tubular adenoma, unilateral																				
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																	P			
Leukemic infiltrates, monocytic,																				
bilateral													P							
Nephropathy, chronic, bilateral	2	3	3	2	1	1	1		1	2	1	1	1	1	2	1	2	1	2	1
Inflammation, lymphocytic, bilateral	1	2	2	1		1														
Microconcretions, tubular, unilateral/																				
bilateral	3																		2	
Pyelonephritis, unilateral/bilateral																				
Pyelitis, suppurative, unilateral/																				
bilateral					3			1										3	3	1
Cortex, protein resorption droplets,																				
bilateral													3							
Necrosis, medullary papilla, unilateral/																				
bilateral					P	P	P	P	P		P	P		P		P	P	P	P	P
Mineralization, uremic, bilateral					2	2		1			2	3		3		2	3		1	
Bacteremia, bilateral																				
Infarction, unilateral, focal																				

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KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL		
Tubular adenoma, unilateral				P								0/4	1/27
Leukemic infiltrates, lymphocytic, unilateral/bilateral												0/4	1/27
Leukemic infiltrates, monocytic, bilateral	P											0/4	2/27
Nephropathy, chronic, bilateral	2	1	1	1	2	1	2	2	2	2	1	4/4	26/27
Inflammation, lymphocytic, bilateral					1	1	1	1		1		4/4	6/27
Microconcretions, tubular, unilateral/ bilateral												1/4	1/27
Pyelonephritis, unilateral/bilateral					3							0/4	1/27
Pyelitis, suppurative, unilateral/ bilateral												0/4	5/27
Cortex, protein resorption droplets, bilateral												0/4	1/27
Necrosis, medullary papilla, unilateral/ bilateral			P	P		P	P				P	0/4	18/27
Mineralization, uremic, bilateral		2		1		1					2	0/4	13/27
Bacteremia, bilateral	P											0/4	1/27
Infarction, unilateral, focal	3											0/4	1/27

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STOMACH	N	N	N	N	L	L	L	L	N	L	L	N	L	L	N	L	L	N	N	N
Leukemic infiltrates, monocytic													P							
Mucosal erosion(s), glandular region										1										
Mineralization, uremic					1	2	1	1			1			1		2	2			
Bacteremia																				
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CECUM	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Nematode parasites in lumen													P							
Bacteremia																				
COLON	N	L	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Nematode parasites in lumen		P		P																

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STOMACH	L	L	N	L	N	L	L	N	N	N	L		
Leukemic infiltrates, monocytic	P											0/4	2/27
Mucosal erosion(s), glandular region							1					0/4	2/27
Mineralization, uremic		1		1		1					2	0/4	12/27
Bacteremia	P											0/4	1/27
DUODENUM	N	N	N	I	N	N	N	N	N	N	N		
JEJUNUM	N	N	N	I	N	I	N	N	N	N	N		
ILEUM	N	I	I	I	N	I	N	N	N	N	N		
CECUM	L	N	N	N	N	N	N	N	N	L	N		
Nematode parasites in lumen										P		0/4	2/27
Bacteremia	P											0/4	1/27
COLON	L	N	N	N	L	N	N	N	L	N	N		
Nematode parasites in lumen	P				P				P			2/4	3/27

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RECTUM	L	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Nematode parasites in lumen	P												P							
SKIN	L	N	N	L	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Epidermal inclusion cyst				P																
Epidermal ulceration																				
Inflammation, dermal, focal, subacute	P														P					
Exudative crusts	P														P					
MAMMARY GLAND	N	N	N	N	N	N	M	N	N	M	N	N	L	M	N	M	M	N	N	M
Galactoceles													P							
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	TS Incidence	SDMS Incidence
RECTUM	N	N	N	N	N	N	N	N	N	N	N		
Nematode parasites in lumen												1/4	1/27
SKIN	N	N	N	N	N	N	N	N	N	L	N		
Leukemic infiltrates, monocytic										P		0/4	1/27
Epidermal inclusion cyst												1/4	0/27
Epidermal ulceration										P		0/4	1/27
Inflammation, dermal, focal, subacute										P		1/4	2/27
Exudative crusts												1/4	1/27
MAMMARY GLAND	N	N	N	N	N	N	N	N	N	N	M		
Galactoceles												0/4	1/20
STERNUM	N	N	N	N	N	N	N	N	N	N	N		
BONE MARROW	N	N	N	N	N	N	N	N	N	N	N		

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7127	80-7141	80-7156	80-7174	80-7109*	80-7113*	80-7117*	80-7124*	80-7130*	80-7140*	80-7144*	80-7146*	80-7154*	80-7160*	80-7161*	80-7162*	80-7169*	80-7118**	80-7125**	80-7131**
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
MESENTERY/ABDOMINAL CAVITY		L			L					L					L					
Inflammation (peritonitis)					P															
Lipogranuloma/fat necrosis		P								P					P					
COAGULATING GLAND				L																
Spermatic granuloma(s), focal				2																
Inflammatory exudate in ducts																				
PREPUTIAL GLAND																			N	
THYMUS					L										L					
Malignant lymphoma															P					
Atrophy					P															
Atrophy with cysts																				
LYMPH NODE(S), NOS								L							L		L			
Monocytic leukemia																				
Malignant lymphoma															P		P			
Lymphoid hyperplasia								2												
NASAL TISSUE																				
Inflammatory exudate																				
PENIS																			N	

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Male Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7134**	80-7137**	80-7153**	80-7157**	80-7158**	80-7163**	80-7167**	80-7172**	80-7177**	80-7179**	80-7180**	TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED													
BY PROTOCOL FOR THIS GROUP													
MESENTERY/ABDOMINAL CAVITY		L	L		L								
Inflammation (peritonitis)												0/1	1/6
Lipogranuloma/fat necrosis		P	P		P							1/1	5/6
COAGULATING GLAND	L								L				
Spermatic granuloma(s), focal	1											1/1	1/2
Inflammatory exudate in ducts									P			0/1	1/2
PREPUTIAL GLAND													
THYMUS					L								
Malignant lymphoma												-	1/3
Atrophy												-	1/3
Atrophy with cysts					P							-	1/3
LYMPH NODE(S), NOS	L				N								
Monocytic leukemia	P											-	1/5
Malignant lymphoma												-	2/5
Lymphoid hyperplasia												-	1/5
NASAL TISSUE											L		
Inflammatory exudate											P	-	1/1
PENIS					N								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = moribund sacrifice
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = spontaneous death
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

PATHOLOGY APPENDIX E

LESION INCIDENCE COMPARISON TABLE - FEMALES

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:INAL REPORT

:EMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
BRAIN	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Astrocytoma	0/43	0/10	0/45	0/10	0/42	0/12	0/41	1/14	0/28	0/20
Ependymoma, anaplastic	0/43	0/10	1/45	0/10	0/42	0/12	0/41	0/14	0/28	0/20
Leukemic infiltrates, lymphocytic	0/43	0/10	0/45	0/10	0/42	1/12	0/41	0/14	0/28	1/20
Leukemic infiltrates, monocytic	0/43	0/10	0/45	2/10	0/42	0/12	0/41	1/14	0/28	1/20
Hemorrhage	0/43	1/10	0/45	2/10	0/42	1/12	0/41	0/14	0/28	2/20
Cerebrum, mineralized, foci	0/43	0/10	0/45	0/10	0/42	0/12	0/41	0/14	0/28	1/20
SPINAL CORD	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Leukemic infiltrates, monocytic	0/43	0/10	0/45	2/10	0/42	1/12	0/41	1/14	0/28	1/20
Hemorrhage	0/43	0/10	0/45	2/10	0/42	1/12	0/41	1/14	0/28	1/20
PITUITARY	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(27)	(19)
Adenoma	27/43	6/10	32/45	8/10	31/42	7/12	32/41	11/14	15/27	10/19
Carcinoma	3/43	1/10	2/45	1/10	4/42	0/12	2/41	0/14	1/27	1/19
Leukemic infiltrates, lymphocytic	0/43	0/10	0/45	1/10	0/42	1/12	0/41	0/14	1/27	3/19
Leukemic infiltrates, monocytic	2/43	1/10	0/45	3/10	0/42	0/12	1/41	4/14	0/27	5/19
Cyst	10/43	2/10	25/45	2/10	20/42	3/12	18/41	5/14	12/27	7/19
Hyperplasia, chromophobe-cell	6/43	0/10	7/45	0/10	5/42	1/12	1/41	1/14	3/27	2/19

de: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

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FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence	RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence	RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence	RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence	RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence	RDX 40.0 mg/kg/day	SDMS Incidence
EYE	(43)		(10)	(3)		(1)	(6)		-	(3)		-	(28)		(20)
Leukemic infiltrates, lymphocytic	0/43		0/10	0/3		1/1	0/6		-	0/3		-	1/28		0/20
Keratitis, chronic	2/43		0/10	1/3		0/1	0/6		-	0/3		-	6/28		2/20
Lens, cataract	14/43		1/10	2/3		0/1	4/6		-	0/3		-	23/28		9/20
Lens-induced inflammation	0/43		1/10	0/3		0/1	1/6		-	0/3		-	9/28		2/20
Degeneration, retinal	11/43		0/10	1/3		0/1	4/6		-	0/3		-	10/28		2/20
Phthisis bulbi	1/43		0/10	1/3		0/1	0/6		-	1/3		-	1/28		0/20
Cyst, choroid	0/43		0/10	1/3		0/1	0/6		-	0/3		-	0/28		0/20
OPTIC NERVE	(43)		(9)	-		-	(1)		-	-		-	(28)		(20)
Degeneration	1/43		0/9	-		-	1/1		-	-		-	0/28		0/20
ADRENAL	(43)		(10)	(2)		(2)	(5)		-	(1)		(1)	(28)		(20)
Pheochromocytoma	2/43		1/10	0/2		0/2	1/5		-	0/1		0/1	2/28		2/20
Pheochromocytoma, malignant	1/43		0/10	0/2		0/2	0/5		-	0/1		0/1	0/28		0/20
Cortex, adenoma	2/43		0/10	0/2		0/2	1/5		-	0/1		0/1	0/28		0/20
Leukemic infiltrates, lymphocytic	1/43		0/10	0/2		1/2	0/5		-	0/1		0/1	1/28		2/20
Leukemic infiltrates, monocytic	5/43		2/10	0/2		0/2	0/5		-	0/1		1/1	1/28		4/20
Cortex, cytomegally	2/43		1/10	0/2		0/2	0/5		-	0/1		0/1	1/28		0/20
Cortex, hyperplasia	2/43		1/10	0/2		0/2	0/5		-	0/1		0/1	1/28		1/20

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EMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

RGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	SDMS Incidence
)RENAL (continued)										
Cortex, metamorphosis, fatty	13/43	6/10	1/2	1/2	0/5	-	0/1	0/1	6/28	5/20
Cortex, angiectasis	24/43	3/10	2/2	0/2	0/5	-	1/1	0/1	11/28	5/20
Medulla, hyperplasia	2/43	1/10	0/2	0/2	1/5	-	0/1	0/1	1/28	0/20
Extamedullary hematopoiesis	1/43	0/10	0/2	0/2	0/5	-	0/1	0/1	0/28	0/20
PLEEN	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Malignant lymphoma	1/43	0/10	1/45	1/10	0/42	3/12	0/41	0/14	2/28	4/20
Monocytic leukemia	15/43	3/10	18/45	5/10	18/42	5/12	10/41	9/14	11/28	9/20
Congestion	1/43	0/10	1/45	1/10	0/42	0/12	2/41	0/14	6/28	0/20
Increased extramedullary hematopoiesis	19/43	4/10	11/45	1/10	12/42	3/12	11/41	3/14	1/28	5/20
Increased pigment	10/43	6/10	21/45	2/10	19/42	3/12	26/41	4/14	10/28	2/20
Infarction	0/43	1/10	0/45	1/10	0/42	0/12	0/41	2/14	0/28	1/20
Fibrosis	0/43	0/10	0/45	1/10	0/42	1/12	1/41	1/14	0/28	0/20
ANCREAS	(43)	(10)	(1)	-	-	(2)	(1)	(2)	(28)	(20)
Islet cell carcinoma	0/43	0/10	1/1	-	-	0/2	0/1	0/2	0/28	0/20
Islet cell adenoma	2/43	1/10	0/1	-	-	0/2	0/1	0/2	0/28	2/20
Leukemic infiltrates, lymphocytic	1/43	0/10	0/1	-	-	1/2	0/1	0/2	1/28	4/20
Leukemic infiltrates, monocytic	3/43	0/10	0/1	-	-	0/2	0/1	1/2	0/28	3/20

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L06121 SN6
FINAL REPORT

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
PANCREAS (continued)										
Hyperplasia, islet cell	2/43	0/10	0/1	-	-	0/2	0/1	0/2	0/28	1/20
Atrophy, acinar cell	11/43	1/10	0/1	-	-	0/2	0/1	0/2	4/28	1/20
Arteritis, chronic	1/43	0/10	0/1	-	-	0/2	0/1	0/2	0/28	0/20
MESENTERIC LYMPH NODE	(42)	(10)	-	(2)	-	(1)	(1)	(4)	(28)	(18)
Monocytic leukemia	3/42	2/10	-	1/2	-	0/1	0/1	4/4	1/28	6/18
Malignant lymphoma	1/42	0/10	-	1/2	-	1/1	0/1	0/4	2/28	4/18
Reticular cell hyperplasia	0/42	0/10	-	0/2	-	0/1	1/1	0/4	0/28	0/18
Angiectasis	0/42	1/10	-	0/2	-	0/1	0/1	0/4	0/28	1/18
OVARY	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Leukemic infiltrates, lymphocytic	0/43	0/10	0/45	1/10	0/42	1/12	0/41	0/14	2/28	1/20
Leukemic infiltrates, monocytic,	2/43	1/10	0/45	3/10	0/42	1/12	0/41	1/14	1/28	2/20
Cyst(s), follicular	8/43	1/10	1/45	0/10	7/42	0/12	3/41	0/14	0/28	2/20
Hematocysts	0/43	0/10	0/45	0/10	0/42	0/12	1/41	0/14	0/28	0/20
UTERUS	(42)	(10)	(11)	(2)	(14)	(2)	(13)	(7)	(28)	(20)
Adenocarcinoma	0/42	0/10	0/11	0/2	0/14	0/2	1/13	0/7	0/28	0/20
Hemangioma	0/42	1/10	0/11	0/2	0/14	0/2	0/13	0/7	0/28	0/20

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FINAL REPORT

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
UTERUS (continued)										
Malignant fibrous histiocytoma	0/42	1/10	0/11	0/2	0/14	0/2	0/13	0/7	0/28	0/20
Endometrial stromal sarcoma	0/42	0/10	0/11	1/2	1/14	0/2	0/13	3/7	0/28	0/20
Endometrial stromal polyp	11/42	1/10	8/11	0/2	11/14	2/2	8/13	1/7	10/28	6/20
Leukemic infiltrates, lymphocytic	0/42	0/10	0/11	0/2	0/14	0/2	0/13	0/7	1/28	0/20
Leukemic infiltrates, monocytic	0/42	0/10	0/11	1/2	0/14	0/2	0/13	0/7	0/28	4/20
Hyperplasia, endometrial	1/42	0/10	1/11	0/2	0/14	0/2	0/13	0/7	2/28	0/20
Cyst, endometrial	4/42	0/10	2/11	0/2	3/14	0/2	3/13	2/7	7/28	2/20
Luminal dilatation-hydrometra	5/42	2/10	2/11	0/2	0/14	0/2	3/13	0/7	0/28	2/20
Luminal dilatation-cellular debris	0/42	0/10	0/11	0/2	1/14	0/2	0/13	0/7	0/28	0/20
Luminal dilatation-hemorrhage	0/42	0/10	0/11	0/2	0/14	0/2	0/13	0/7	1/28	0/20
URINARY BLADDER	(42)	(9)	-	(1)	-	-	-	(2)	(28)	(20)
Papilloma	0/42	0/9	-	0/1	-	-	-	0/2	1/28	0/20
Leukemic infiltrates, lymphocytic	0/42	0/9	-	0/1	-	-	-	0/2	1/28	1/20
Leukemic infiltrates, monocytic	1/42	0/9	-	1/1	-	-	-	1/2	0/28	2/20
LUNG-MAINSTEM BRONCHI	(42)	(10)	-	(7)	(4)	(4)	(2)	(8)	(28)	(20)
Bronchiolar-alveolar carcinoma	0/43	0/10	-	0/7	1/4	0/4	0/2	0/8	0/28	0/20
Bronchiolar-alveolar adenoma	3/43	0/10	-	0/7	0/4	0/4	1/2	0/8	0/28	0/20

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- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL REPORT

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
LUNG-MAINSTEM BRONCHI (continued)										
Carcinoma, metastatic, mammary	0/43	0/10	-	0/7	0/4	0/4	0/2	0/8	0/28	1/20
Carcinoma, metastatic, squamous cell	0/43	1/10	-	0/7	0/4	0/4	0/2	0/8	0/28	1/20
Malignant fibrous histiocytoma, metastatic	0/43	1/10	-	0/7	0/4	0/4	0/2	0/8	0/28	0/20
Leukemic infiltrates, lymphocytic	1/43	0/10	-	0/7	0/4	2/4	0/2	0/8	2/28	4/20
Leukemic infiltrates, monocytic	7/43	1/10	-	5/7	0/4	1/4	0/2	4/8	5/28	8/20
Alveolar macrophages	6/43	0/10	-	0/7	0/4	1/4	0/2	0/8	5/28	1/20
Lymphoid infiltrates, peribronchial/iolar	43/43	10/10	-	5/7	3/4	1/4	2/2	4/8	27/28	12/20
Bronchopneumonia	0/43	0/10	-	0/7	0/4	0/4	0/2	0/8	0/28	1/20
Congestion, agonal	1/43	0/10	-	1/7	2/4	0/4	0/2	0/8	2/28	2/20
Hemorrhage, focal	0/43	0/10	-	0/7	1/4	1/4	0/2	0/8	0/28	0/20
Alveolar septae, fibrinoid degeneration	0/43	0/10	-	0/7	0/4	0/4	0/2	0/8	0/28	1/20
ESOPHAGUS	(43)	(10)	-	-	-	-	-	-	(28)	(20)
TRACHEA	(43)	(10)	-	-	-	-	-	-	(28)	(20)
Leukemic infiltrates, lymphocytic	0/43	0/10	-	-	-	-	-	-	0/28	1/20
Inflammation, chronic	8/43	3/10	-	-	-	-	-	-	16/28	2/20

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L06121 SN6
FINAL REPORT

FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
TRACHEA (continued)										
Mucocele(s), submucosal	4/43	0/10	-	-	-	-	-	-	1/28	1/20
THYROID	(43)	(10)	-	-	(3)	-	(1)	-	(28)	(20)
C-cell carcinoma	1/43	0/10	-	-	2/3	-	1/1	-	0/28	0/20
C-cell adenoma	9/43	1/10	-	-	1/3	-	0/1	-	5/28	5/20
Follicular cystadenoma	0/43	0/10	-	-	0/3	-	0/1	-	1/28	0/20
Hyperplasia, C-cell	15/43	1/10	-	-	0/3	-	0/1	-	7/28	7/20
Cystic follicle(s)	4/43	2/10	-	-	0/3	-	0/1	-	5/28	4/20
PARATHYROID	(42)	(10)	-	-	-	-	-	-	(28)	(19)
HEART	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Neurilemmoma	0/43	0/10	0/45	0/10	0/42	0/12	0/41	0/14	1/28	0/20
Leukemic infiltrates, lymphocytic	0/43	0/10	1/45	1/10	0/42	1/12	0/41	0/14	1/28	3/20
Leukemic infiltrates, monocytic	3/43	1/10	0/45	5/10	0/42	3/12	3/41	4/14	1/28	5/20
Myocarditis, chronic	30/43	4/10	43/45	5/10	40/42	8/12	37/41	10/14	26/28	11/20
Auricular thrombosis	0/43	0/10	0/45	0/10	1/42	1/12	0/41	0/14	1/28	2/20

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'EMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

)RGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
IVER	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Neoplastic nodule	3/43	0/10	1/45	0/10	1/42	0/12	0/41	0/14	3/28	1/20
Hepatocellular carcinoma	0/43	0/10	1/45	0/10	0/42	0/12	0/41	0/14	0/28	0/20
Malignant fibrous histiocytoma	0/42	0/10	0/45	0/10	2/42	0/12	0/41	0/14	0/28	1/20
Leukemic infiltrates, lymphocytic	1/43	0/10	1/45	1/10	0/42	3/12	0/41	0/14	2/28	4/20
Leukemic infiltrates, monocytic	14/43	3/10	15/45	5/10	17/42	4/12	9/41	9/14	11/28	9/20
Focus of hyperplasia with cystic degeneration	0/43	0/10	2/45	0/10	2/42	0/12	2/41	0/14	0/28	0/20
Area(s) of hyperplasia with cystic degeneration	1/43	0/10	1/45	0/10	5/42	1/12	7/41	0/14	0/28	0/20
Foci of cellular alteration-basophilic	41/43	8/10	45/45	7/10	40/42	5/12	40/41	7/14	23/28	8/20
Foci of cellular alteration-eosinophilic	5/43	1/10	6/45	0/10	3/42	0/12	4/41	0/14	3/28	1/20
Foci of cellular alteration-clear cells	0/43	0/10	1/45	0/10	3/42	0/12	3/41	0/14	0/28	0/20
Area of cellular alteration-clear cells	2/43	0/10	3/45	0/10	12/42	0/12	5/41	0/14	5/28	0/20
Foci of cellular alteration-mixed cells	2/43	1/10	2/45	0/10	4/42	0/12	1/41	0/14	4/28	0/20
Area of cellular alteration-mixed cells	0/43	0/10	1/45	0/10	1/42	0/12	0/41	0/14	0/28	0/20
Hyperplasia, regenerative	0/43	0/10	2/45	1/10	2/42	0/12	1/41	0/14	1/28	0/20
Necrosis, random	2/43	0/10	0/45	0/10	1/42	0/12	1/41	0/14	0/28	1/20
Necrosis, agonal	0/43	1/10	0/45	1/10	1/42	2/12	0/41	2/14	0/28	0/20
Bile duct proliferation	14/43	2/10	11/45	5/10	19/42	6/12	25/41	8/14	4/28	11/20

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FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	SDMS Incidence
LIVER (continued)										
Cholangiofibrosis	6/43	1/10	4/45	2/10	5/42	1/12	5/41	3/14	0/28	3/20
Metamorphosis, fatty	2/43	1/10	0/45	1/10	0/42	6/12	0/41	4/14	2/28	5/20
Extramedullary hematopoiesis	3/43	1/10	0/45	0/10	1/42	1/12	0/41	1/14	0/28	0/20
Microgranulomas	10/43	1/10	19/45	2/10	12/42	1/12	17/41	1/14	4/28	4/20
Mononuclear cell infiltrates, sinusoidal	0/43	0/10	0/45	0/10	0/42	0/12	0/41	0/14	1/28	0/20
Cyst	0/43	0/10	0/45	0/10	1/42	0/12	0/41	0/14	0/28	0/20
KIDNEY	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(14)	(28)	(20)
Tubular cell carcinoma	0/43	0/10	1/45	0/10	0/42	0/12	0/41	0/14	0/28	0/20
Tubular cell adenoma	0/43	0/10	0/45	0/10	1/42	0/12	0/41	0/14	0/28	0/20
Leukemic infiltrates, lymphocytic	0/43	0/10	0/45	1/10	0/42	2/12	0/41	0/14	2/28	2/20
Leukemic infiltrates, monocytic	1/43	0/10	0/45	4/10	1/42	1/12	2/41	5/14	0/28	4/20
Nephropathy, chronic	43/43	8/10	44/45	8/10	42/42	9/12	41/41	10/14	28/28	19/20
Inflammation, lymphocytic	8/43	3/10	8/45	0/10	21/42	0/12	14/41	1/14	11/28	1/20
Microconcretions, tubular	12/43	0/10	7/45	1/10	13/42	1/12	2/41	1/14	4/28	5/20
Cortex, increased pigment	0/43	0/10	0/45	1/10	0/42	1/12	0/41	2/14	0/28	2/20
Cortex, protein resorption droplets	2/43	3/10	2/45	3/10	3/42	0/12	2/41	1/14	1/28	1/20
Cortex, cyst	0/43	0/10	0/45	0/10	0/42	0/12	1/41	0/14	1/28	0/20

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'EMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
IDNEY (continued)										
Infarction	1/43	0/10	2/45	0/10	0/42	0/12	0/41	0/14	0/28	1/20
Lipomatosis, interstitial	0/43	0/10	1/45	0/10	0/42	0/12	0/41	0/14	0/28	0/20
Pelvic dilatation	0/43	1/10	0/45	0/10	0/42	0/12	0/41	0/14	0/28	0/20
Bacteremia	0/43	0/10	0/45	0/10	0/42	0/12	0/41	1/14	0/28	0/20
STOMACH	(43)	(10)	-	-	(1)	-	-	(1)	(28)	(20)
Leukemic infiltrates, lymphocytic	0/43	0/10	-	-	0/1	-	-	0/1	1/28	1/20
Leukemic infiltrates, monocytic	0/43	0/10	-	-	0/1	-	-	0/1	0/28	1/20
Inflammation, forestomach	0/43	1/10	-	-	0/1	-	-	0/1	1/28	1/20
Mucosal erosion(s), glandular region	2/43	1/10	-	-	1/1	-	-	0/1	0/28	0/20
Mucosal ulcer, glandular region	0/43	0/10	-	-	0/1	-	-	1/1	0/28	4/20
Mucosal ulcer, forestomach	0/43	0/10	-	-	0/1	-	-	0/1	0/28	2/20
Mineralization, uremic	0/43	0/10	-	-	0/1	-	-	0/1	0/28	1/20
DUODENUM	(43)	(10)	-	-	-	(1)	-	-	(28)	(19)
JEJUNUM	(43)	(8)	-	-	-	(1)	-	-	(28)	(19)

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LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
ILEUM	(43)	(8)	-	-	-	(1)	-	-	(28)	(18)
Leukemic infiltrates, lymphocytic	0/43	0/8	-	-	-	0/1	-	-	1/28	0/18
CECUM	(43)	(8)	-	-	-	-	-	-	(28)	(19)
Leukemic infiltrates, monocytic	0/43	0/8	-	-	-	-	-	-	0/28	3/19
Nematode parasites in lumen	0/43	0/8	-	-	-	-	-	-	5/28	2/19
Inflammation with ulceration	0/43	0/8	-	-	-	-	-	-	0/28	2/19
COLON	(43)	(8)	-	-	-	(2)	-	-	(28)	(19)
Leukemic infiltrates, monocytic	0/43	0/8	-	-	-	0/2	-	-	0/28	1/19
Nematode parasites in lumen	2/43	0/8	-	-	-	0/2	-	-	7/28	3/19
RECTUM	(43)	(8)	-	-	-	-	-	-	(28)	(19)
Leukemic infiltrates, monocytic	0/43	0/8	-	-	-	-	-	-	0/28	1/19
Nematode parasites in lumen	6/43	0/8	-	-	-	-	-	-	2/28	0/19
SKIN	(43)	(10)	(5)	(1)	(2)	(1)	(4)	(5)	(28)	(20)
Squamous cell carcinoma	0/43	1/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	1/20
Basal cell tumor	0/43	0/10	0/5	0/1	0/2	0/1	1/4	0/5	0/28	0/20
Basal cell tumor, cystic	1/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	0/20

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LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
SKIN (continued)										
Malignant fibrous histiocytoma	0/43	1/10	0/5	1/1	0/2	0/1	0/4	1/5	1/28	1/20
Leukemic infiltrates, lymphocytic	0/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	1/20
Leukemic infiltrates, monocytic	0/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	1/20
Inflammation, dermal	0/43	1/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	1/20
Exudative crusts	0/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	2/20
Epidermal inclusion cyst	0/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	1/28	0/20
Epidermal ulceration	0/43	0/10	0/5	0/1	0/2	0/1	0/4	0/5	0/28	2/20
MAMMARY GLAND	(40)	(10)	(17)	(1)	(15)	(6)	(12)	(3)	(28)	(17)
Carcinosarcoma	0/40	0/10	0/17	0/1	0/15	0/6	0/12	0/3	0/28	1/17
Carcinoma	0/40	0/10	1/17	0/1	1/15	0/6	1/12	0/3	0/28	0/17
Adenoma	1/40	0/10	1/17	0/1	0/15	1/6	0/12	0/3	0/28	0/17
Fibroadenoma	10/40	1/10	7/17	0/1	11/15	2/6	6/12	2/3	2/28	2/17
Galactoceles	7/40	4/10	9/17	0/1	5/15	3/6	7/12	0/3	4/28	2/17
Cystic hyperplasia	1/40	3/10	7/17	1/1	2/15	2/6	1/12	1/3	4/28	1/17
STERNUM	(43)	(10)	-	-	-	-	-	-	(28)	(20)
Bone resorption and fibrosis	0/43	0/10	-	-	-	-	-	-	0/28	1/20

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'EMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

IRGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
ONE MARROW	(43)	(10)	(2)	(1)	(3)	-	-	-	(28)	(20)
Leukemic infiltrates, lymphocytic	1/43	0/10	0/2	1/1	0/3	-	-	-	1/28	3/20
Leukemic infiltrates, monocytic	0/43	0/10	0/2	0/1	0/3	-	-	-	0/28	1/20
Megakaryocytosis	1/43	0/10	0/2	0/1	0/3	-	-	-	0/28	0/20
Myelofibrosis	7/43	0/10	1/2	0/1	1/3	-	-	-	8/28	1/20
Hypocellular	0/43	0/10	0/2	0/1	0/3	-	-	-	0/28	1/20
'ISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP										
MESENTERY/ABDOMINAL CAVITY	(4)	(1)	(5)	(2)	(3)	-	(5)	(1)	(4)	(3)
Lipogranuloma/fat necrosis	4/4	1/1	5/5	2/2	3/3	-	5/5	1/1	4/4	3/3
CLITORAL GLAND	(2)	(1)	(4)	(1)	(1)	(1)	(1)	-	(4)	-
Carcinoma	1/2	0/1	0/4	0/1	1/1	0/1	1/1	-	1/4	-
Adenoma	1/2	1/1	4/4	1/1	0/1	1/1	0/1	-	3/4	-
LYMPH NODE(S), NOS	(2)	(3)	(2)	(4)	-	(2)	(1)	(7)	(6)	(4)
Monocytic leukemia	1/2	1/3	0/2	2/4	-	0/2	0/1	5/7	0/6	1/4
Malignant lymphoma	1/2	0/3	1/2	1/4	-	2/2	0/1	0/7	2/6	3/4
Carcinoma, metastatic, C-cell	1/2	0/3	0/2	0/4	-	0/2	0/1	0/7	0/6	0/4
Carcinoma, metastatic, squamous cell	0/2	1/3	0/2	0/4	-	0/2	0/1	0/7	0/6	0/4

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FEMALE F344 RATS

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP (continued)										
LYMPH NODE(S), NOS (continued)										
Carcinoma, metastatic, clitoral	0/2	0/3	0/2	0/4	-	0/2	0/1	0/7	1/6	0/4
Malignant fibrous histiocytoma, metastatic	0/2	1/3	0/2	0/4	-	0/2	0/1	0/7	0/6	0/4
Lymphoid hyperplasia	0/2	0/3	1/2	0/4	-	0/2	0/1	0/7	3/6	0/4
Angiectasis	0/2	0/3	0/2	0/4	-	1/2	0/1	1/7	0/6	0/4
Lymphadenitis	0/2	0/3	0/2	1/4	-	0/2	0/1	0/7	0/6	0/4
SALIVARY GLAND	-	-	-	(1)	-	-	-	(2)	(1)	(1)
Leukemic infiltrates, monocytic	-	-	-	1/1	-	-	-	0/2	0/1	0/1
HARDERIAN GLAND	-	-	-	-	(1)	-	(1)	-	-	(1)
Leukemic infiltrates, lymphocytic	-	-	-	-	0/1	-	0/1	-	-	1/1
Leukemic infiltrates, monocytic	-	-	-	-	0/1	-	1/1	-	-	0/1
Dacryoadenitis	-	-	-	-	1/1	-	0/1	-	-	0/1
THYMUS	-	-	-	-	-	(1)	-	-	-	(1)
Malignant lymphoma	-	-	-	-	-	1/1	-	-	-	1/1
FEMUR/VERTEBRAE	-	-	(2)	(1)	(4)	-	-	-	-	-
MUSCLE, NOS	-	-	-	-	-	-	(1)	-	-	-
LARYNX	-	-	-	-	-	-	-	(1)	-	-

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PATHOLOGY APPENDIX F

HISTOPATHOLOGY LESION SEVERITY AND INCIDENCE TABLE - FEMALES

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F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6583	80-6584	80-6590	80-6591	80-6592	80-6593	80-6595	80-6596	80-6599	80-6601	80-6602	80-6603	80-6607	80-6608	80-6609	80-6610	80-6611	80-6612	80-6613	80-6614
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L	L
Adenoma	P	P		P	P	P	P			P	P		P		P	P			P	P
Carcinoma												P								
Leukemic infiltrates, monocytic								P												
Cyst			P					P	P		P								P	
Hyperplasia, chromophobe-cell														2				1		
EYE	NN	NL	LL	NN	NL	NN	NN	NN	LL	LM	NN	NN	NN	NN	NN	LL	NL	NN	NN	NN
Keratitis, chronic, unilateral,																				
focal/multifocal			4													3				
Lens, cataract, unilateral/bilateral		P			P					P						P	P			
Lens-induced inflammation, unilateral/																				
bilateral																				
Degeneration, retinal, unilateral/																				
bilateral			3		3				3	3						3	3			

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6615	80-6616	80-6622	80-6624	80-6626	80-6629	80-6630	80-6633	80-6634	80-6636	80-6637	80-6638	80-6639	80-6640	80-6641	80-6643	80-6644	80-6645	80-6652	80-6653
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
PITUITARY	L	L	L	L	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L
Adenoma	P	P			P		P	P	P			P	P		P	P		P	P	P
Carcinoma				P							P									
Leukemic infiltrates, monocytic			P																	
Cyst			P			P								P				P		P
Hyperplasia, chromophobe-cell						2								2			1			
EYE	NN	NN	NN	NL	NN	NN	NN	NN	NN	NL	LL	LL	LL	LL	NN	NN	NL	NL	NN	NN
Keratitis, chronic, unilateral,																				
focal/multifocal																				
Lens, cataract, unilateral/bilateral				P						P	P	P	P	P			P	P		
Lens-induced inflammation, unilateral/																				
bilateral																				
Degeneration, retinal, unilateral/																				
bilateral				3							3		3	2						

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**	TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	L		
Hemorrhage, focal													1	0/43	1/10
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N		
PITUITARY	L	L	N	L	N	L	L	L	L	L	L	L	L		
Adenoma		P		P		P		P	P		P		P	27/43	6/10
Carcinoma										P				3/43	1/10
Leukemic infiltrates, monocytic				P										2/43	1/10
Cyst							P					P		10/43	2/10
Hyperplasia, chromophobe-cell	2													6/43	0/10
EYE	NN	LL	NN	NN	NN	NN	NN	NL	NN	NN	NN	NN	NN		
Keratitis, chronic, unilateral, focal/multifocal														2/43	0/10
Lens, cataract, unilateral/bilateral		P						P						14/43	1/10
Lens-induced inflammation, unilateral/bilateral								P						0/43	1/10
Degeneration, retinal, unilateral/bilateral		3												11/43	0/10

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F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6583	80-6584	80-6590	80-6591	80-6592	80-6593	80-6595	80-6596	80-6599	80-6601	80-6602	80-6603	80-6607	80-6608	80-6609	80-6610	80-6611	80-6612	80-6613	80-6614
EYE (continued)																				
Phthisis bulbi, unilateral									P											
OPTIC NERVE	NN	NN	NM	NN	NN	NN	NN	NN	NM	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Degeneration, unilateral																				
ADRENAL	LL	LL	NN	LL	NN	NN	NL	LL	NL	LL	NL	LL	LL	LL	NN	LL	NL	LL	LL	NN
Pheochromocytoma, unilateral							P			P										
Pheochromocytoma, malignant, unilateral																				
Cortex, adenoma, unilateral				P															P	
Leukemic infiltrates, lymphocytic, bilateral																			P	
Leukemic infiltrates, monocytic, unilateral/bilateral								P												
Cortex, cytomegally, focal, unilateral													3							
Cortex, hyperplasia, focal, unilateral																				
Cortex, metamorphosis, fatty, unilateral/bilateral								2			1	1	2	1			1			
Cortex, angiectasis, unilateral/bilateral	1	2		1					2	1		1		1		1	2	2		

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6615	80-6616	80-6622	80-6624	80-6626	80-6629	80-6630	80-6633	80-6634	80-6636	80-6637	80-6638	80-6639	80-6640	80-6641	80-6643	80-6644	80-6645	80-6652	80-6653
EYE (continued)																				
Phthisis bulbi, unilateral																				
OPTIC NERVE	NN	NN	NN	NL	NN	NN	NN	NN	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN
Degeneration, unilateral				2																
ADRENAL	LL	NL	LL	LL	LL	LL	NL	NL	LL	LL	NL	LM	NL	LL	NL	NL	LL	LL	LL	NL
Pheochromocytoma, unilateral																				
Pheochromocytoma, malignant, unilateral																				
Cortex, adenoma, unilateral																				
Leukemic infiltrates, lymphocytic, bilateral																				
Leukemic infiltrates, monocytic, unilateral/bilateral	P		P														P			
Cortex, cytomegally, focal, unilateral																			3	
Cortex, hyperplasia, focal, unilateral		3												1						
Cortex, metamorphosis, fatty, unilateral/bilateral		1				1		1				1	1	1						4
Cortex, angiectasis, unilateral/ bilateral	1			2	1		1	1	2	1	1				2	1		1	1	

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**							TS Incidence	SDMS Incidence
EYE (continued)																					
Phthisis bulbi, unilateral																				1/43	0/10
OPTIC NERVE	NN	NN	NN	NN	NN	MM	NN	NM	NN	NN	NN	NN	NN								
Degeneration, unilateral																				1/43	0/9
ADRENAL	LL	LL	LL	LL	LL	LN	NN	NN	LL	LL	NL	LL	LL								
Pheochromocytoma, unilateral				P																2/43	1/10
Pheochromocytoma, malignant, unilateral			P																	1/43	0/10
Cortex, adenoma, unilateral																				2/43	0/10
Leukemic infiltrates, lymphocytic, bilateral																				1/43	0/10
Leukemic infiltrates, monocytic, unilateral/bilateral			P	P								P								5/43	2/10
Cortex, cytomegally, focal, unilateral											2									2/43	1/10
Cortex, hyperplasia, focal, unilateral													2							2/43	1/10
Cortex, metamorphosis, fatty, unilateral/bilateral					3	1			1	1		1	1							13/43	6/10
Cortex, angiectasis, unilateral/ bilateral	1	1		1					1	1										24/43	3/10

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ADRENAL (continued)																				
Medulla, hyperplasia, focal, unilateral								2												
Extamedullary hematopoiesis, focal, unilateral		1																		
SPLEEN	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L	N	L	N	L	L
Malignant lymphoma																			P	
Monocytic leukemia		P			P			P	P					P	P					
Congestion, diffuse						1														
Increased extramedullary hematopoiesis	1	2	2				2			1	2	2					1			2
Increased pigment, diffuse													2							
Infarction, focal																				
PANCREAS	L	L	N	N	L	N	L	L	N	N	N	N	N	N	N	N	N	L	L	L
Islet cell adenoma																				
Leukemic infiltrates, lymphocytic																			P	
Leukemic infiltrates, monocytic								P												
Hyperplasia, islet cell, focal	1																			
Atrophy, acinar cell, focal/multifocal		1			1													1	3	3
Arteritis, chronic, focal							3													

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ADRENAL (continued)																				
Medulla, hyperplasia, focal, unilateral						1														
Extamedullary hematopoiesis, focal, unilateral																				
SPLEEN	L	L	L	L	L	N	L	L	N	L	L	L	N	L	L	L	L	L	L	L
Malignant lymphoma																				
Monocytic leukemia	P		P					P		P	P			P			P			
Congestion, diffuse																				
Increased extramedullary hematopoiesis		2		1	1							1		1		1		1	1	1
Increased pigment, diffuse					1		2	2							1	1		2	1	1
Infarction, focal																				
PANCREAS	L	L	L	N	L	L	L	L	N	N	N	N	N	L	N	L	L	N	N	N
Islet cell adenoma								P								P				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic			P														P			
Hyperplasia, islet cell, focal							1													
Atrophy, acinar cell, focal/multifocal	2	3			1	1								1						
Arteritis, chronic, focal																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**								TS Incidence	SDMS Incidence
ADRENAL (continued)																						
Medulla, hyperplasia, focal, unilateral					2																2/43	1/10
Extamedullary hematopoiesis, focal, unilateral																					1/43	0/10
SPLEEN	L	L	L	L	L	N	L	L	L	L	L	L	L									
Malignant lymphoma																					1/43	0/10
Monocytic leukemia	P		P	P							P	P									15/43	3/10
Congestion, diffuse																					1/43	0/10
Increased extramedullary hematopoiesis		1			4		2	1					1								19/43	4/10
Increased pigment, diffuse		2					1	2	2	2	2		2								10/43	6/10
Infarction, focal												2									0/43	1/10
PANCREAS	L	N	N	N	L	N	N	N	N	N	N	L	N									
Islet cell adenoma					P																2/43	1/10
Leukemic infiltrates, lymphocytic																					1/43	0/10
Leukemic infiltrates, monocytic																					3/43	0/10
Hyperplasia, islet cell, focal																					2/43	0/10
Atrophy, acinar cell, focal/multifocal	1											2									11/43	1/10
Arteritis, chronic, focal																					1/43	0/10

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MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	L	N	N	N	N	N	N	M	N	N	N	L	N
Monocytic leukemia								P												
Malignant lymphoma																			P	
Angiectasis, multifocal																				
OVARY	NN	LL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NL	NN	LL	LL	NN	NN	NN	NN
Leukemic infiltrates, monocytic, unilateral/bilateral		P																		
Cyst(s), follicular, unilateral/ bilateral													P		P	P				
UTERUS	N	N	L	N	N	N	N	N	M	N	L	N	N	L	L	N	L	N	L	N
Hemangioma																				
Malignant fibrous histiocytoma																				
Endometrial stromal polyp			P								P			P			P			
Hyperplasia, endometrial																				
Cyst, endometrial																			P	
Luminal dilatation-hydrometra															P					

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MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N
Monocytic leukemia																	P			
Malignant lymphoma																				
Angiectasis, multifocal																				
OVARY	NN	NN	NL	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NL	LL	NN	NN	NN
Leukemic infiltrates, monocytic, unilateral/bilateral																	P			
Cyst(s), follicular, unilateral/bilateral			P	P												P	P			
UTERUS	N	L	N	N	N	L	N	N	L	N	L	L	N	N	N	N	L	L	N	L
Hemangioma																				
Malignant fibrous histiocytoma																				
Endometrial stromal polyp		P				P						P						P		P
Hyperplasia, endometrial																				2
Cyst, endometrial						P					P						P			
Luminal dilatation-hydrometra		P							P											P

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619**	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**								TS Incidence	SDMS Incidence
MESENTERIC LYMPH NODE	N	N	L	L	N	N	N	N	N	N	L	L	N									
Monocytic leukemia			P	P								P									3/42	2/10
Malignant lymphoma																					1/42	0/10
Angiectasis, multifocal											2										0/42	1/10
OVARY	NN	NN	NL	LL	NN	NN	NN	NN	NM	NN	NN	NL	NN									
Leukemic infiltrates, monocytic, unilateral/bilateral				P																	2/43	1/10
Cyst(s), follicular, unilateral/ bilateral			P									P									8/43	1/10
UTERUS	L	L	N	N	L	L	N	N	L	N	N	N	L									
Hemangioma						P															0/42	1/10
Malignant fibrous histiocytoma					P																0/42	1/10
Endometrial stromal polyp	P	P							P												11/42	1/10
Hyperplasia, endometrial																					1/42	0/10
Cyst, endometrial																					4/42	0/10
Luminal dilatation-hydrometra	P					P							P								5/42	2/10

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URINARY BLADDER	N	L	N	N	N	N	N	N	M	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic		P																		
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Bronchiolar-alveolar adenoma									P											
Carcinoma, metastatic, squamous cell																				
Malignant fibrous histiocytoma,																				
metastatic																				
Leukemic infiltrates, lymphocytic																			P	
Leukemic infiltrates, monocytic		P						P												
Alveolar macrophages, focal/multifocal		2	1														1	1	1	
Lymphoid infiltrates,																				
peribronchial/iolar, focal	2	1	2	1	1	1	1	1	2	2	1	1	2	2	2	1	1	2	1	2
Congestion, agonal, diffuse				1																
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	N	L	N	L	N	N	N	L	N	N	N	N	L	L	L	N	L	N	N	N
Inflammation, chronic		1		1									1	1	1		1			
Mucocele(s), submucosal, focal								2												

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Bronchiolar-alveolar adenoma						P							P							
Carcinoma, metastatic, squamous cell																				
Malignant fibrous histiocytoma,																				
metastatic																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P		P											P			P			
Alveolar macrophages, focal/multifocal														1						
Lymphoid infiltrates,																				
peribronchial/iolar, focal	1	1	1	1	2	2	2	2	2	2	1	2	1	2	2	1	1	2	2	2
Congestion, agonal, diffuse																				
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	N	N	N	L	N	N	N	N	N	N	N	N	L	N	N	L	N	N	L	N
Inflammation, chronic													1						1	
Mucocele(s), submucosal, focal				2												2				

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ORGAN / Lesion — Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**	TS Incidence	SDMS Incidence
URINARY BLADDER	N	N	N	M	N	N	N	N	N	N	N	N	N		
Leukemic infiltrates, monocytic														1/42	0/9
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L		
Bronchiolar-alveolar adenoma														3/43	0/10
Carcinoma, metastatic, squamous cell										P				0/43	1/10
Malignant fibrous histiocytoma, metastatic					P									0/43	1/10
Leukemic infiltrates, lymphocytic														1/43	0/10
Leukemic infiltrates, monocytic			P	P										7/43	1/10
Alveolar macrophages, focal/multifocal														6/43	0/10
Lymphoid infiltrates, peribronchial/iolar, focal	2	2	1	1	1	1	1	1	1	1	2	2	2	43/43	10/10
Congestion, agonal, diffuse														1/43	0/10
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N		
TRACHEA	N	L	N	N	N	L	N	N	N	L	L	N	N		
Inflammation, chronic						1				1	1			8/43	3/10
Mucocele(s), submucosal, focal		1												4/43	0/10

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THYROID	NL	NL	NL	LL	NL	NN	LL	LL	NN	NN	NN	NN	NN	NL	LL	NL	NL	NN	LL	NN
C-cell carcinoma, unilateral																			P	
C-cell adenoma, unilateral/bilateral	P							P									P			
Hyperplasia, C-cell, unilateral/																				
bilateral, focal		2		2	1		1	1								1			2	
Cystic follicle(s), unilateral/																				
bilateral			P											P	P					
PARATHYROID	NN	NN	MM	NN	NN	NN	NN	NN	NM	NN	NN	NN	NM	NN	NN	NN	NN	NM	NM	NM
HEART	L	L	N	L	N	N	L	N	L	L	L	L	N	L	L	L	L	L	L	L
Leukemic infiltrates, monocytic		P																		
Myocarditis, chronic, focal/multifocal	2			1			1		1	2	1	1		1	1	2	1	2	1	2
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule		P			P	P														
Leukemic infiltrates, lymphocytic																			P	
Leukemic infiltrates, monocytic		P			P			P	P						P					
Area(s) of hyperplasia with cystic																				
degeneration																				

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THYROID	NL	NN	NL	NN	NN	NN	NL	NN	NN	LL	LL	NL	LL	NN	NL	NL	NN	NL	NL	NL
C-cell carcinoma, unilateral																				
C-cell adenoma, unilateral/bilateral			P													P		P	P	
Hyperplasia, C-cell, unilateral/																				
bilateral, focal	2						1			1	1	1	1		1					1
Cystic follicle(s), unilateral/																				
bilateral																				
PARATHYROID	NM	NM	NN	NM	NM	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NM	NM	NN	NM
HEART	L	L	N	N	L	L	N	L	L	L	L	L	L	N	L	L	L	L	N	L
Leukemic infiltrates, monocytic	P																P			
Myocarditis, chronic, focal/multifocal		1			1	1		1	1	1	1	1	2		1	1		1		2
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P		P					P		P	P			P			P			
Area(s) of hyperplasia with cystic																				
degeneration																		P		

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**	TS Incidence	SDMS Incidence
THYROID	NL	NL	NL	NL	NN	NN	LL	NL	NN	NN	NN	NN	NN		
C-cell carcinoma, unilateral														1/43	0/10
C-cell adenoma, unilateral/bilateral	P	P		P										9/43	1/10
Hyperplasia, C-cell, unilateral/															
bilateral, focal							1							15/43	1/10
Cystic follicle(s), unilateral/															
bilateral			P	P				P						4/43	2/10
PARATHYROID	NN	NN	NM	NN	NN	NM	NM	NN	NM	NN	NN	NM	NN		
HEART	L	L	L	L	N	N	L	N	N	N	L	N	L		
Leukemic infiltrates, monocytic				P										3/43	1/10
Myocarditis, chronic, focal/multifocal	2	1	2	1			1				1		1	30/43	4/10
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L		
Neoplastic nodule														3/43	0/10
Leukemic infiltrates, lymphocytic														1/43	0/10
Leukemic infiltrates, monocytic	P		P	P							P	P		14/43	3/10
Area(s) of hyperplasia with cystic															
degeneration														1/43	0/10

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ORGAN Lesion / Accession Number	80-6583	80-6584	80-6590	80-6591	80-6592	80-6593	80-6595	80-6596	80-6599	80-6601	80-6602	80-6603	80-6607	80-6608	80-6609	80-6610	80-6611	80-6612	80-6613	80-6614
LIVER (continued)																				
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P	P
Foci of cellular alteration-eosinophilic		P										P	P					P		
Area of cellular alteration-clear cells												P								
Foci of cellular alteration-mixed cells																				
Necrosis, random, focal		1						1												
Necrosis, agonal, centrilobular																				
focal/multifocal/diffuse																				
Bile duct proliferation, focal/																				
multifocal	1	2		1															2	1
Cholangiofibrosis, focal/multifocal								1											3	
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse		2									2									
Extramedullary hematopoiesis, focal/																				
multifocal	1		1																	
Microgranulomas, focal/multifocal						1					1				1			1		

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6615	80-6616	80-6622	80-6624	80-6626	80-6629	80-6630	80-6633	80-6634	80-6636	80-6637	80-6638	80-6639	80-6640	80-6641	80-6643	80-6644	80-6645	80-6652	80-6653
LIVER (continued)																				
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P
Foci of cellular alteration-eosinophilic																				
Area of cellular alteration-clear cells		P																		
Foci of cellular alteration-mixed cells											P			P						
Necrosis, random, focal																				
Necrosis, agonal, centrilobular																				
focal/multifocal/diffuse																				
Bile duct proliferation, focal/																				
multifocal	2		1		1			1		1	1					1	2			
Cholangiofibrosis, focal/multifocal	2													2			1			
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Extramedullary hematopoiesis, focal/																				
multifocal												2								
Microgranulomas, focal/multifocal						1						2		2				2		1

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LIVER (continued)																						
Foci of cellular alteration-basophilic	P	P	P	P	P		P	P		P	P	P	P								41/43	8/10
Foci of cellular alteration-eosinophilic			P										P								5/43	1/10
Area of cellular alteration-clear cells																					2/43	0/10
Foci of cellular alteration-mixed cells											P										2/43	1/10
Necrosis, random, focal																					2/43	0/10
Necrosis, agonal, centrilobular																						
focal/multifocal/diffuse						2															0/43	1/10
Bile duct proliferation, focal/																						
multifocal			3									1	1								14/43	2/10
Cholangiofibrosis, focal/multifocal			1									2									6/43	1/10
Metamorphosis, fatty, periportal/																						
centrilobular/random, focal/																						
multifocal/diffuse									2												2/43	1/10
Extramedullary hematopoiesis, focal/																						
multifocal								1													3/43	1/10
Microgranulomas, focal/multifocal		2								1											10/43	1/10

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KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Nephropathy, chronic, unilateral/																				
bilateral	2	2	1	2	1	1	3	2	1	2	1	1	2	1	1	2	2	2	2	2
Inflammation, lymphocytic, unilateral/																				
bilateral						1	1			1		1								
Microconcretions, tubular, unilateral/																				
bilateral		2		1	1											1	1	1		
Cortex, protein resorption droplets,																				
bilateral																			2	
Infarction, unilateral/bilateral, focal																				
Pelvic dilatation, bilateral																				
STOMACH	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N
Inflammation, forestomach																				
Mucosal erosion(s), glandular region					2														2	
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, monocytic, unilateral/bilateral	P																			
Nephropathy, chronic, unilateral/bilateral	1	1	1	1	1	1	1	2	1	1	2	1	1	1	2	2	1	1	1	1
Inflammation, lymphocytic, unilateral/bilateral									1		1			1					1	
Microconcretions, tubular, unilateral/bilateral									1				1	1	1		1			1
Cortex, protein resorption droplets, bilateral							2													
Infarction, unilateral/bilateral, focal			3																	
Pelvic dilatation, bilateral																				
STOMACH	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Inflammation, forestomach																				
Mucosal erosion(s), glandular region																				
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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ORGAN Lesion / Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**								TS Incidence	SDMS Incidence
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL									
Leukemic infiltrates, monocytic,																						
unilateral/bilateral																					1/43	0/10
Nephropathy, chronic, unilateral/																						
bilateral	2	2	2	2	2	1	1	2	3		3		3								43/43	8/10
Inflammation, lymphocytic, unilateral/																						
bilateral					1						1		2								8/43	3/10
Microconcretions, tubular, unilateral/																						
bilateral																					12/43	0/10
Cortex, protein resorption droplets,																						
bilateral								2				2	3								2/43	3/10
Infarction, unilateral/bilateral, focal																					1/43	0/10
Pelvic dilatation, bilateral					2																0/43	1/10
STOMACH	N	N	N	N	N	N	N	N	N	L	N	N	N									
Inflammation, forestomach										3											0/43	1/10
Mucosal erosion(s), glandular region																					2/43	1/10
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N									

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JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CECUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
COLON	N	L	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Nematode parasites in lumen		P											P							
RECTUM	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	L	L	N
Nematode parasites in lumen													P					P	P	
SKIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Squamous cell carcinoma																				
Basal cell tumor, cystic																				
Malignant fibrous histiocytoma																				
Inflammation, dermal																				
MAMMARY GLAND	M	N	L	N	M	L	L	N	N	N	N	L	N	N	N	N	N	N	M	N
Adenoma																				

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JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ILEUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
CECUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
COLON	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Nematode parasites in lumen																				
RECTUM	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	L	N	N	N
Nematode parasites in lumen												P					P			
SKIN	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Squamous cell carcinoma																				
Basal cell tumor, cystic				P																
Malignant fibrous histiocytoma																				
Inflammation, dermal																				
MAMMARY GLAND	N	L	N	L	L	N	L	L	N	L	L	L	N	N	N	L	N	N	N	N
Adenoma								P												

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JEJUNUM	N	N	N	N	I	I	N	N	N	N	N	N	N		
ILEUM	N	N	N	N	I	I	N	N	N	N	N	N	N		
CECUM	N	N	N	N	I	I	N	N	N	N	N	N	N		
COLON	N	N	N	N	I	I	N	N	N	N	N	N	N		
Nematode parasites in lumen														2/43	0/9
RECTUM	N	N	L	N	I	I	N	N	N	N	N	N	N		
Nematode parasites in lumen			P											6/43	0/8
SKIN	N	N	N	N	L	N	N	N	N	L	L	N	N		
Squamous cell carcinoma										P				0/43	1/10
Basal cell tumor, cystic														1/43	0/10
Malignant fibrous histiocytoma					P									0/43	1/10
Inflammation, dermal											2			0/43	1/10
MAMMARY GLAND	N	N	N	N	L	N	N	L	L	N	L	L	L		
Adenoma														1/40	0/10

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MAMMARY GLAND (continued)																				
Fibroadenoma			P			P	P													
Galactoceles						P	P					P								
Cystic hyperplasia							2													
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	N	N	N	N	N	L	L	N	N	N	N	N	L	N	N	N	L	N
Leukemic infiltrates, lymphocytic																			P	
Megakaryocytosis, diffuse								2												
Myelofibrosis, focal								2	1						1					
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
MESENTERY/ABDOMINAL CAVITY												L						L		
Lipogranuloma/fat necrosis												P						P		
CLITORAL GLAND											L									
Carcinoma																				
Adenoma											P									

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MAMMARY GLAND (continued)																				
Fibroadenoma		P			P		P	P		P	P					P				
Galactoceles				P			P					P				P				
Cystic hyperplasia																				
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
BONE MARROW	N	N	L	N	N	L	L	N	N	N	N	L	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Megakaryocytosis, diffuse																				
Myelofibrosis, focal			3			1	2					2								
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
MESENTERY/ABDOMINAL CAVITY																				
Lipogranuloma/fat necrosis																				
CLITORAL GLAND													L							
Carcinoma													P							
Adenoma																				

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MAMMARY GLAND (continued)																						
Fibroadenoma													P								10/40	1/10
Galactoceles					P				P		P		P								7/40	4/10
Cystic hyperplasia								2	2			2									1/40	3/10
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N									
BONE MARROW	N	N	N	N	N	N	N	N	N	N	N	N	N									
Leukemic infiltrates, lymphocytic																					1/43	0/10
Megakaryocytosis, diffuse																					1/43	0/10
Myelofibrosis, focal																					7/43	0/10
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP																						
MESENTERY/ABDOMINAL CAVITY	L	L								L												
Lipogranuloma/fat necrosis	P	P								P											4/4	1/1
CLITORAL GLAND											L											
Carcinoma																					1/2	0/1
Adenoma											P										1/2	1/1

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
LYMPH NODE(S), NOS																				
Monocytic leukemia																			L	
Malignant lymphoma																			P	
Carcinoma, metastatic, C-cell																			P	
Carcinoma, metastatic, squamous cell																				
Malignant fibrous histiocytoma, metastatic																				

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F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6615	80-6616	80-6622	80-6624	80-6626	80-6629	80-6630	80-6633	80-6634	80-6636	80-6637	80-6638	80-6639	80-6640	80-6641	80-6643	80-6644	80-6645	80-6652	80-6653
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP (continued)																				
LYMPH NODE(S), NOS																	L			
Monocytic leukemia																	P			
Malignant lymphoma																				
Carcinoma, metastatic, C-cell																				
Carcinoma, metastatic, squamous cell																				
Malignant fibrous histiocytoma,																				
metastatic																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SOMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6654	80-6655	80-6657	80-6589*	80-6605*	80-6619*	80-6635*	80-6604**	80-6617**	80-6620**	80-6625**	80-6632**	80-6649**								TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP (continued)																						
LYMPH NODE(S), NOS				L	L					L												
Monocytic leukemia				P																	1/2	1/3
Malignant lymphoma																					1/2	0/3
Carcinoma, metastatic, C-cell																					1/2	0/3
Carcinoma, metastatic, squamous cell										P											0/2	1/3
Malignant fibrous histiocytoma, metastatic					P																0/2	1/3

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Ependymoma, anaplastic																				
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Adenoma		P	P	P	P	P	P			P	P	P	P	P		P		P	P	P
Carcinoma	P								P											
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Cyst			P			P	P	P	P		P	P		P		P		P	P	P
Hyperplasia, chromophobe-cell															2		1			
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule		P																		
Hepatocellular carcinoma																				

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS - terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Ependymoma, anaplastic																				
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Adenoma	P	P		P	P			P	P	P	P	P	P		P	P			P	P
Carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Cyst	P		P			P	P	P		P		P		P			P	P		
Hyperplasia, chromophobe-cell			1				1							1				1		
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule																				
Hepatocellular carcinoma							P													

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	L	N	N	N	N	L	N	L	N	N	L							
Ependymoma, anaplastic					P																1/45	0/10
Leukemic infiltrates, monocytic										P					P						0/45	2/10
Hemorrhage, focal										2		1									0/45	2/10
SPINAL CORD	N	N	N	N	N	N	N	N	N	L	N	N	N	N	L							
Leukemic infiltrates, monocytic										P					P						0/45	2/10
Hemorrhage, focal										1					2						0/45	2/10
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L							
Adenoma	P			P	P	P		P	P	P	P	P	P		P						32/45	8/10
Carcinoma							P														2/45	1/10
Leukemic infiltrates, lymphocytic							P														0/45	1/10
Leukemic infiltrates, monocytic										P		P			P						0/45	3/10
Cyst	P		P	P				P		P											25/45	2/10
Hyperplasia, chromophobe-cell		1																			7/45	0/10
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Neoplastic nodule																					1/45	0/10
Hepatocellular carcinoma																					1/45	0/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
LIVER (continued)																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic		P								P	P					P	P		P	P
Focus of hyperplasia with cystic degeneration									P											
Area(s) of hyperplasia with cystic degeneration																				
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic	P																			
Foci of cellular alteration-clear cells																				
Area of cellular alteration-clear cells												P								
Foci of cellular alteration-mixed cells						P										P				
Area of cellular alteration-mixed cells																				
Hyperplasia, regenerative, focal																				
Necrosis, agonal, centrilobular focal/multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal			1					1					1		1		1			
Cholangiofibrosis, focal/multifocal															1		1			

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
LIVER (continued)																				
Leukemic infiltrates, lymphocytic												P								
Leukemic infiltrates, monocytic	P	P		P	P			P		P							P			
Focus of hyperplasia with cystic																				
degeneration																				
Area(s) of hyperplasia with cystic																				
degeneration						P														
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic		P								P			P	P					P	
Foci of cellular alteration-clear cells																				
Area of cellular alteration-clear cells															P		P			
Foci of cellular alteration-mixed cells																				
Area of cellular alteration-mixed cells									P											
Hyperplasia, regenerative, focal													3							
Necrosis, agonal, centrilobular																				
focal/multifocal/diffuse																				
Bile duct proliferation, focal/																				
multifocal	1		1	1								2					1			
Cholangiofibrosis, focal/multifocal							1					2								

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Leukemic infiltrates, lymphocytic							P														1/45	1/10
Leukemic infiltrates, monocytic		P						P	P	P		P			P						15/45	5/10
Focus of hyperplasia with cystic degeneration			P																		2/45	0/10
Area(s) of hyperplasia with cystic degeneration																					1/45	0/10
Foci of cellular alteration-basophilic	P	P	P	P	P	P			P	P	P	P	P	P							45/45	7/10
Foci of cellular alteration-eosinophilic																					6/45	0/10
Foci of cellular alteration-clear cells					P																1/45	0/10
Area of cellular alteration-clear cells																					3/45	0/10
Foci of cellular alteration-mixed cells																					2/45	0/10
Area of cellular alteration-mixed cells																					1/45	0/10
Hyperplasia, regenerative, focal					2								2								2/45	1/10
Necrosis, agonal, centrilobular focal/multifocal/diffuse								1													0/45	1/10
Bile duct proliferation, focal/ multifocal				1					2	2	1	2			1						11/45	5/10
Cholangiofibrosis, focal/multifocal								2				2									4/45	2/10

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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
LIVER (continued)																				
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Microgranulomas, focal/multifocal			1				1		1		1		1	1		2	2		2	
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	LL	LL	LL	LL	LL
Tubular cell carcinoma, unilateral		P																		
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Nephropathy, chronic, unilateral/																				
bilateral	3	2	1	2	1	1	1	1	1	1		1	2	1	1	2	1	1	1	1
Inflammation, lymphocytic, unilateral/																				
bilateral	2			1	1		1						1							
Microconcretions, tubular, unilateral/																				
bilateral		1												1						
Cortex, increased pigment, bilateral																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
LIVER (continued)																				
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Microgranulomas, focal/multifocal		1				2			1	1				2	1					
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Tubular cell carcinoma, unilateral																				
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Nephropathy, chronic, unilateral/																				
bilateral	2	2	1	2	2	1	1	1	2	2	2	1	1	1	2	1	1	1	1	2
Inflammation, lymphocytic, unilateral/																				
bilateral		1									1									
Microconcretions, tubular, unilateral/																				
bilateral	1			1		1					1					1				
Cortex, increased pigment, bilateral																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] = terminal sacrifice [illegible] = DMS [illegible] spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Metamorphosis, fatty, periportal/																						
centrilobular/random, focal/																						
multifocal/diffuse							2														0/45	1/10
Microgranulomas, focal/multifocal	1		2	1	2						1		1								19/45	2/10
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL							
Tubular cell carcinoma, unilateral																					1/45	0/10
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral							P														0/45	1/10
Leukemic infiltrates, monocytic,																						
unilateral/bilateral								P	P	P					P						0/45	4/10
Nephropathy, chronic, unilateral/																						
bilateral	1	1	1	1	1	1		1		1	2	1	1	1	2						44/45	8/10
Inflammation, lymphocytic, unilateral/																						
bilateral				1																	8/45	0/10
Microconcretions, tubular, unilateral/																						
bilateral														1							7/45	1/10
Cortex, increased pigment, bilateral										2											0/45	1/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
KIDNEY (continued)																				
Cortex, protein resorption droplets, bilateral																				
Infarction, unilateral/bilateral, focal																		1		
Lipomatosis, interstitial, focal, unilateral																				3
HEART	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1	1	1	1		1	1	1	1	1	1	1	1	1	1	1	1	2	2
SPLEEN	L	L	L	L	L	N	L	L	L	L	L	L	L	N	L	L	L	L	L	L
Malignant lymphoma																				
Monocytic leukemia		P								P	P					P	P	P	P	P
Congestion, diffuse	1																			
Increased extramedullary hematopoiesis				1			1	1												
Increased pigment, diffuse	2		2	1	2				2			1	2		2					
Infarction, focal																				
Fibrosis, focal/multifocal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
KIDNEY (continued)																				
Cortex, protein resorption droplets, bilateral												2								1
Infarction, unilateral/bilateral, focal																				
Lipomatosis, interstitial, focal, unilateral																				
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic												P								
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1	1	1	1	1	1	1	1	1	1		1	2	1	1	1	1	2	2
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L	L	L	L
Malignant lymphoma												P								
Monocytic leukemia	P	P		P	P			P		P				P			P			
Congestion, diffuse																				
Increased extramedullary hematopoiesis		1				2	1		1				1				1		1	
Increased pigment, diffuse			1			2	2		2		2		1			2		2	1	3
Infarction, focal																				
Fibrosis, focal/multifocal																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						IS Incidence	SDMS Incidence
KIDNEY (continued)																						
Cortex, protein resorption droplets,																						
bilateral								2			2	2									2/45	3/10
Infarction, unilateral/bilateral, focal				1																	2/45	0/10
Lipomatosis, interstitial, focal,																						
unilateral																					1/45	0/10
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Leukemic infiltrates, lymphocytic							P														1/45	1/10
Leukemic infiltrates, monocytic								P	P	P		P			P						0/45	5/10
Myocarditis, chronic, focal/multifocal	1	1	2	1	2	1			2		1		1	1							43/45	5/10
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Malignant lymphoma							P														1/45	1/10
Monocytic leukemia		P			P			P	P	P		P			P						18/45	5/10
Congestion, diffuse						1															1/45	1/10
Increased extramedullary hematopoiesis	1													3							11/45	1/10
Increased pigment, diffuse	2		2	2							2		2								21/45	2/10
Infarction, focal												3									0/45	1/10
Fibrosis, focal/multifocal								2													0/45	1/10

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
OVARY	NN	NN	NN	NN	NM	NN	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cyst(s), follicular, unilateral/																				
bilateral								P												
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE																				
Leukemic infiltrates, lymphocytic																				
Keratitis, chronic, unilateral,																				
focal/multifocal																				
Lens, cataract, unilateral/bilateral																				
Degeneration, retinal, unilateral/																				
bilateral																				
Phthisis bulbi, unilateral																				
Cyst, choroid, unilateral																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
OVARY	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cyst(s), follicular, unilateral/																				
bilateral																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE	L	L											LL							
Leukemic infiltrates, lymphocytic																				
Keratitis, chronic, unilateral,																				
focal/multifocal		3																		
Lens, cataract, unilateral/bilateral		P											P							
Degeneration, retinal, unilateral/																				
bilateral													3							
Phthisis bulbi, unilateral	P																			
Cyst, choroid, unilateral		P																		

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
OVARY	NN	NN	NN	NN	NN	NN	LL	LL	NN	NN	NN	LL	NN	NM	LL							
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral							P														0/45	1/10
Leukemic infiltrates, monocytic,																						
unilateral/bilateral								P				P			P						0/45	3/10
Cyst(s), follicular, unilateral/																						
bilateral																					1/45	0/10
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP																						
EYE							LL															
Leukemic infiltrates, lymphocytic							P														0/3	1/1
Keratitis, chronic, unilateral,																						
focal/multifocal																					1/3	0/1
Lens, cataract, unilateral/bilateral																					2/3	0/1
Degeneration, retinal, unilateral/																						
bilateral																					1/3	0/1
Phthisis bulbi, unilateral																					1/3	0/1
Cyst, choroid, unilateral																					1/3	0/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL																			L	
Leukemic infiltrates, lymphocytic,																				
bilateral																				
Cortex, metamorphosis, fatty,																				
unilateral/bilateral																				
Cortex, angiectasis, unilateral/																				
bilateral																			1	
PANCREAS																		L		
Islet cell carcinoma																		P		
MESENTERIC LYMPH NODE																				
Monocytic leukemia																				
Malignant lymphoma																				
UTERUS		L	L				L				L								L	
Endometrial stromal sarcoma																				
Endometrial stromal polyp			P				P				P									
Leukemic infiltrates, monocytic																				
Hyperplasia, endometrial		2																		
Cyst, endometrial																			P	

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] = terminal sacrifice [illegible] = [illegible] death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL		L																		
Leukemic infiltrates, lymphocytic,																				
bilateral																				
Cortex, metamorphosis, fatty,																				
unilateral/bilateral		1																		
Cortex, angiectasis, unilateral/																				
bilateral		1																		
PANCREAS																				
Islet cell carcinoma																				
MESENTERIC LYMPH NODE																				
Monocytic leukemia																				
Malignant lymphoma																				
UTERUS			L		L				L									L		
Endometrial stromal sarcoma																				
Endometrial stromal polyp					P				P									P		
Leukemic infiltrates, monocytic																				
Hyperplasia, endometrial																				
Cyst, endometrial			P																	

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
ADRENAL							LL							LL								
Leukemic infiltrates, lymphocytic,																						
bilateral							P														0/2	1/2
Cortex, metamorphosis, fatty,																						
unilateral/bilateral														2							1/2	1/2
Cortex, angiectasis, unilateral/																						
bilateral																					2/2	0/2
PANCREAS																						
Islet cell carcinoma																					1/1	
MESENTERIC LYMPH NODE							L	L														
Monocytic leukemia								P													-	1/2
Malignant lymphoma							P														-	1/2
UTERUS		L	L					L	N													
Endometrial stromal sarcoma								P													0/11	1/2
Endometrial stromal polyp		P	P																		8/11	0/2
Leukemic infiltrates, monocytic								P													0/11	1/2
Hyperplasia, endometrial																					1/11	0/2
Cyst, endometrial																					2/11	0/2

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
UTERUS (continued)																				
Luminal dilatation-hydrometra		P																		
URINARY BLADDER																				
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI																				
Leukemic infiltrates, monocytic																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal																				
Congestion, agonal, diffuse																				
SKIN	N		N																	
Malignant fibrous histiocytoma																				
MAMMARY GLAND					L							L	L		L	L		L		
Carcinoma												P								
Adenoma																				
Fibroadenoma					P								P		P					
Galactoceles															P	P		P		
Cystic hyperplasia																3		2		

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
UTERUS (continued)																				
Luminal dilatation-hydrometra			P																	
URINARY BLADDER																				
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI																				
Leukemic infiltrates, monocytic																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal																				
Congestion, agonal, diffuse																				
SKIN			N				N								N					
Malignant fibrous histiocytoma																				
MAMMARY GLAND						L	L						L		L	L		L	L	L
Carcinoma																				
Adenoma													P							
Fibroadenoma						P												P		P
Galactoceles						P	P						P			P		P		P
Cystic hyperplasia							2								2				2	

continued next page

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FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
UTERUS (continued)																						
Luminal dilatation-hydrometra																					2/11	0/2
URINARY BLADDER								L														
Leukemic infiltrates, monocytic								P													-	1/1
LUNG-MAINSTEM BRONCHI								L	L	L		L	L	L	L							
Leukemic infiltrates, monocytic								P	P	P		P			P						-	5/7
Lymphoid infiltrates,																						
peribronchial/iolar, focal										2		1	2	1	1						-	5/7
Congestion, agonal, diffuse													2								-	1/7
SKIN														L								
Malignant fibrous histiocytoma														P							0/5	1/1
MAMMARY GLAND	L	L			L		L															
Carcinoma																					1/17	0/1
Adenoma																					1/17	0/1
Fibroadenoma	P																				7/17	0/1
Galactoceles																					9/17	0/1
Cystic hyperplasia		2			3		2														7/17	1/1

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FINAL REPORT
F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
BONE MARROW																				
Leukemic infiltrates, lymphocytic																				
Myelofibrosis, focal																				
MESENTERY/ABDOMINAL CAVITY							L	L										L		
Lipogranuloma/fat necrosis							P	P										P		
CLITORAL GLAND																L				
Adenoma																P				
LYMPH NODE(S), NOS																				
Monocytic leukemia																				
Malignant lymphoma																				
Lymphoid hyperplasia																				
Lymphadenitis																				
SALIVARY GLAND																				
Leukemic infiltrates, monocytic																				
FEMUR/VERTEBRAE																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
BONE MARROW									N								L			
Leukemic infiltrates, lymphocytic																				
Myelofibrosis, focal																	1			
MESENTERY/ABDOMINAL CAVITY																L				L
Lipogranuloma/fat necrosis																P				P
CLITORAL GLAND						L									L					
Adenoma						P									P					
LYMPH NODE(S), NOS												L			L					
Monocytic leukemia																				
Malignant lymphoma												P								
Lymphoid hyperplasia															2					
Lymphadenitis																				
SALIVARY GLAND																				
Leukemic infiltrates, monocytic																				
FEMUR/VERTEBRAE									N								N			

continued next page

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
BONE MARROW							L															
Leukemic infiltrates, lymphocytic							P														0/2	1/1
Myelofibrosis, focal																					1/2	0/1
MESENTERY/ABDOMINAL CAVITY								L					L									
Lipogranuloma/fat necrosis								P					P								5/5	2/2
CLITORAL GLAND		L				L																
Adenoma		P				P															4/4	1/1
LYMPH NODE(S), NOS							L	L				L		L								
Monocytic leukemia								P				P									0/2	2/4
Malignant lymphoma							P														1/2	1/4
Lymphoid hyperplasia																					1/2	0/4
Lymphadenitis														2							0/2	1/4
SALIVARY GLAND								L														
Leukemic infiltrates, monocytic								P													-	1/1
FEMUR/VERTEBRAE							N															

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Adenoma	P	P	P	P	P	P			P	P	P			P	P	P	P	P	P	P
Carcinoma								P												
Leukemic infiltrates, lymphocytic																				
Cyst	P					P	P		P	P	P	P		P	P		P			
Hyperplasia, chromophobe-cell							2					2	1							
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule																		P		
Malignant fibrous histiocytoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic		P						P	P	P	P	P						P	P	P

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L	L	L	L	L	L
Adenoma	P		P		P	P		P			P	P		P	P		P	P	P	P
Carcinoma		P		P					P											
Leukemic infiltrates, lymphocytic																				
Cyst	P		P			P	P	P	P	P						P				P
Hyperplasia, chromophobe-cell							1									2				
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule																				
Malignant fibrous histiocytoma				P															P	
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic	P		P					P				P	P	P		P				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	L	N	N	N	N								
Leukemic infiltrates, monocytic										P											0/42	1/12
Hemorrhage, focal										3											0/42	1/12
SPINAL CORD	N	N	N	N	N	N	N	N	N	L	N	N	N	N								
Leukemic infiltrates, monocytic										P											0/42	1/12
Hemorrhage, focal										3											0/42	1/12
PITUITARY	L	L	L	N	N	N	L	L	L	L	L	L	L	L								
Adenoma	P	P					P	P	P	P	P	P		P							31/42	7/12
Carcinoma																					4/42	0/12
Leukemic infiltrates, lymphocytic			P																		0/42	1/12
Cyst	P		P							P			P								20/42	3/12
Hyperplasia, chromophobe-cell													2								5/42	1/12
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L								
Neoplastic nodule																					1/42	0/12
Malignant fibrous histiocytoma																					2/42	0/12
Leukemic infiltrates, lymphocytic			P			P					P										0/42	3/12
Leukemic infiltrates, monocytic		P		P						P			P	P							17/42	4/12

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
LIVER (continued)																				
Focus of hyperplasia with cystic degeneration					P															
Area(s) of hyperplasia with cystic degeneration							P									P				
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic			P																	
Foci of cellular alteration-clear cells						P														
Area of cellular alteration-clear cells					P				P				P	P	P		P		P	
Foci of cellular alteration-mixed cells	P							P		P										P
Area of cellular alteration-mixed cells																				
Hyperplasia, regenerative, focal	3																			
Necrosis, random, focal																			3	
Necrosis, agonal, centrilobular focal/multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal		1	1			1		1	1	1		1			1					
Cholangiofibrosis, focal/multifocal		1										1								

continued next page

Code: 1 = minimal 2 = mild 3 = moderate 4 = severe P = present N = within normal limits L = lesion present M = tissue not present I = tissue section inadequate * = spontaneous death ** = moribund sacrifice
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
LIVER (continued)																				
Focus of hyperplasia with cystic																				
degeneration																		P		
Area(s) of hyperplasia with cystic																				
degeneration						P							P							
Foci of cellular alteration-basophilic	P	P	P	P		P	P	P	P	P	P	P		P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic			P				P													
Foci of cellular alteration-clear cells														P						P
Area of cellular alteration-clear cells								P	P						P		P			
Foci of cellular alteration-mixed cells																				
Area of cellular alteration-mixed cells							P													
Hyperplasia, regenerative, focal										2										
Necrosis, random, focal																				
Necrosis, agonal, centrilobular																				
focal/multifocal/diffuse					2															
Bile duct proliferation, focal/																				
multifocal	1	1							1	1		1		1	1	1			2	
Cholangiofibrosis, focal/multifocal														1			1		2	

continued next page

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
LIVER (continued)																						
Focus of hyperplasia with cystic																						
degeneration																					2/42	0/12
Area(s) of hyperplasia with cystic																						
degeneration	P						P														5/42	1/12
Foci of cellular alteration-basophilic	P	P			P		P	P		P		P									40/42	5/12
Foci of cellular alteration-eosinophilic																					3/42	0/12
Foci of cellular alteration-clear cells																					3/42	0/12
Area of cellular alteration-clear cells		P																			12/42	0/12
Foci of cellular alteration-mixed cells																					4/42	0/12
Area of cellular alteration-mixed cells																					1/42	0/12
Hyperplasia, regenerative, focal																					2/42	0/12
Necrosis, random, focal																					1/42	0/12
Necrosis, agonal, centrilobular																						
focal/multifocal/diffuse									3		3										1/42	2/12
Bile duct proliferation, focal/																						
multifocal	2	2	1	2		1			1				3	2							19/42	6/12
Cholangiofibrosis, focal/multifocal														2							5/42	1/12

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
LIVER (continued)																				
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Extramedullary hematopoiesis, focal/																				
multifocal																				
Microgranulomas, focal/multifocal			1				1								1				2	1
Cyst					P															
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Tubular cell adenoma, unilateral					P															
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Nephropathy, chronic, unilateral/																				
bilateral	1	2	1	1	2	1	1	1	1	1	1	1	1	1	1	2	1	1	1	2
Inflammation, lymphocytic, unilateral/																				
bilateral		1		1	1		1		1	1			1	1		1				2

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LIVER (continued)																				
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				
Extramedullary hematopoiesis, focal/																				
multifocal					1															
Microgranulomas, focal/multifocal	1		2			1					1	1								2
Cyst																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Tubular cell adenoma, unilateral																				
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral	P																			
Nephropathy, chronic, unilateral/																				
bilateral	1	1	1	2	1	1	1	1	1	1	1	2	1	2	2	1	1	2	1	2
Inflammation, lymphocytic, unilateral/																				
bilateral				1		1	1		1		1	1	1	1	2			1		1

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

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LIVER (continued)																						
Metamorphosis, fatty, periportal/																						
centrilobular/random, focal/																						
multifocal/diffuse			2	3					3		3		3	2							0/42	6/12
Extramedullary hematopoiesis, focal/																						
multifocal								1													1/42	1/12
Microgranulomas, focal/multifocal		1										1									12/42	1/12
Cyst																					1/42	0/12
KIDNEY	LL	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	LL	LL								
Tubular cell adenoma, unilateral																					1/42	0/12
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral			P			P															0/42	2/12
Leukemic infiltrates, monocytic,																						
unilateral/bilateral										P											1/42	1/12
Nephropathy, chronic, unilateral/																						
bilateral	2	1	1	1	1		2		2		2	1	1	1							42/42	9/12
Inflammation, lymphocytic, unilateral/																						
bilateral																					21/42	0/12

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
KIDNEY (continued)																				
Microconcretions, tubular, unilateral/																				
bilateral			1	1			1	1	1					1	1		1			
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets,																				
bilateral																2				2
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	2	1	1	1	1	1	1	1	2	1	1	1	1	1	2	1	2	2	2
Auricular thrombosis																				
SPLEEN	N	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L	L	L
Malignant lymphoma																				
Monocytic leukemia		P						P	P	P	P	P		P				P	P	P
Increased extramedullary hematopoiesis					1						2					1	1			
Increased pigment, diffuse			1	2	1	1							2		2	2	2			
Fibrosis, focal/multifocal																				

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KIDNEY (continued)																				
Microconcretions, tubular, unilateral/ bilateral		1	1			1										1				
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets, bilateral															2					
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	N	L	L
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1	2	1	1	1	2	1	1	1	2	2	1	1	1	1			1	1
Auricular thrombosis					P															
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Malignant lymphoma																				
Monocytic leukemia	P		P					P				P	P	P		P				
Increased extramedullary hematopoiesis		2			3	1		1	2		1				1		1			
Increased pigment, diffuse				2		1	1			1	1				2		2	2	2	2
Fibrosis, focal/multifocal																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
KIDNEY (continued)																						
Microconcretions, tubular, unilateral/																						
bilateral		1							1												13/42	1/12
Cortex, increased pigment, bilateral			2																		0/42	1/12
Cortex, protein resorption droplets,																						
bilateral																					3/42	0/12
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L								
Leukemic infiltrates, lymphocytic			P																		0/42	1/12
Leukemic infiltrates, monocytic										P			P	P							0/42	3/12
Myocarditis, chronic, focal/multifocal	1	1		1	1	1	1	1	1		1	1									40/42	8/12
Auricular thrombosis									P												1/42	1/12
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L								
Malignant lymphoma			P			P					P										0/42	3/12
Monocytic leukemia		P		P	P					P			P	P							18/42	5/12
Increased extramedullary hematopoiesis							1	2	1												12/42	3/12
Increased pigment, diffuse	2						2		2			2									19/42	3/12
Fibrosis, focal/multifocal				3																	0/42	1/12

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FINAL REPORT
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
OVARY	NN	NL	NN	NN	NN	NN	NN	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cyst(s), follicular, unilateral/																				
bilateral		P							P											
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE									LL	L				N						
Lens, cataract, unilateral/bilateral									P	P										
Lens-induced inflammation,																				
unilateral/bilateral																				
Degeneration, retinal, unilateral/																				
bilateral									2	3										
OPTIC NERVE																				
Degeneration, unilateral																				

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OVARY	NN	NN	NN	NL	NN	NN	NN	NN	NL	NN	NN	NN	NN	NL	NN	NL	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cyst(s), follicular, unilateral/																				
bilateral				P					P					P		P				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE					L					L	L									
Lens, cataract, unilateral/bilateral					P						P									
Lens-induced inflammation,																				
unilateral/bilateral										2										
Degeneration, retinal, unilateral/																				
bilateral					3						3									
OPTIC NERVE										L										
Degeneration, unilateral										2										

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
OVARY	NL	NN	NL	NN	NN	NN	NN	NN	NN	LL	NN	NN	NN	NN								
Leukemic infiltrates, lymphocytic,																						
unilateral/bilateral			P																		0/42	1/12
Leukemic infiltrates, monocytic,																						
unilateral/bilateral										P											0/42	1/12
Cyst(s), follicular, unilateral/																						
bilateral	P																				7/42	0/12
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP																						
EYE																						
Lens, cataract, unilateral/bilateral																					4/6	-
Lens-induced inflammation,																						
unilateral/bilateral																					1/6	-
Degeneration, retinal, unilateral/																						
bilateral																					4/6	-
OPTIC NERVE																						
Degeneration, unilateral																					1/1	-

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL										L										
Pheochromocytoma, unilateral																				
Cortex, adenoma, unilateral										P										
Medulla, hyperplasia, focal,																				
unilateral																				
PANCREAS																				
Leukemic infiltrates, lymphocytic																				
MESENTERIC LYMPH NODE																				
Malignant lymphoma																				
UTERUS	L		L	L	L	L		L					L	L						
Endometrial stromal sarcoma				P																
Endometrial stromal polyp					P	P		P					P	P						
Cyst, endometrial	P												P							
Luminal dilatation-cellular debris			P																	
LUNG-MAINSTEM BRONCHI					L		L		L											
Bronchiolar-alveolar carcinoma							P													
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
ADRENAL		L	L		N		N													
Pheochromocytoma, unilateral			P																	
Cortex, adenoma, unilateral																				
Medulla, hyperplasia, focal, unilateral		2																		
PANCREAS																				
Leukemic infiltrates, lymphocytic																				
MESENTERIC LYMPH NODE																				
Malignant lymphoma																				
UTERUS			L	L		L			L			L					L			
Endometrial stromal sarcoma																				
Endometrial stromal polyp			P	P		P			P			P					P			
Cyst, endometrial						P														
Luminal dilatation-cellular debris																				
LUNG-MAINSTEM BRONCHI					L															
Bronchiolar-alveolar carcinoma																				
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				

continued next page

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TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
ADRENAL																						
Pheochromocytoma, unilateral																					1/5	-
Cortex, adenoma, unilateral																					1/5	-
Medulla, hyperplasia, focal,																						
unilateral																					1/5	-
PANCREAS			L											N								
Leukemic infiltrates, lymphocytic			P																		-	1/2
MESENTERIC LYMPH NODE											L											
Malignant lymphoma											P										-	1/1
UTERUS			L	L																		
Endometrial stromal sarcoma																					1/14	0/2
Endometrial stromal polyp			P	P																	11/14	2/2
Cyst, endometrial																					3/14	0/2
Luminal dilatation-cellular debris																					1/14	0/2
LUNG-MAINSTEM BRONCHI			L		L						L			L								
Bronchiolar-alveolar carcinoma																					1/4	0/4
Leukemic infiltrates, lymphocytic			P								P										0/4	2/4
Leukemic infiltrates, monocytic														P							0/4	1/4

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TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LUNG-MAINSTEM BRONCHI (continued)																				
Alveolar macrophages, focal/																				
multifocal																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal					1		2													
Congestion, agonal, diffuse					1				1											
Hemorrhage, focal/multifocal									2											
THYROID																L				
C-cell carcinoma, unilateral																P				
C-cell adenoma, unilateral/bilateral																				
STOMACH																				
Mucosal erosion(s), glandular region																				
DUODENUM																				
JEJUNUM																				
ILEUM																				
COLON																				
SKIN																N				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
LUNG-MAINSTEM BRONCHI (continued)																				
Alveolar macrophages, focal/																				
multifocal																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal					1															
Congestion, agonal, diffuse																				
Hemorrhage, focal/multifocal																				
THYROID						L						LL								
C-cell carcinoma, unilateral						P														
C-cell adenoma, unilateral/bilateral												P								
STOMACH					L															
Mucosal erosion(s), glandular region					2															
DUODENUM																				
JEJUNUM																				
ILEUM																				
COLON																				
SKIN	N																			

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
LUNG-MAINSTEM BRONCHI (continued)																						
Alveolar macrophages, focal/																						
multifocal														2							0/4	1/4
Lymphoid infiltrates,																						
peribronchial/iolar, focal														1							3/4	1/4
Congestion, agonal, diffuse																					2/4	0/4
Hemorrhage, focal/multifocal					3																1/4	1/4
THYROID																						
C-cell carcinoma, unilateral																					2/3	-
C-cell adenoma, unilateral/bilateral																					1/3	-
STOMACH																						
Mucosal erosion(s), glandular region																					1/1	-
DUODENUM								N														
JEJUNUM					N																	
ILEUM					N																	
COLON									N				N									
SKIN										N												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND			L				L					L	L		L		L			L
Carcinoma																				
Adenoma																				
Fibroadenoma			P				P					P	P		P		P			
Galactoceles			P									P								P
Cystic hyperplasia																				
BONE MARROW																	L			
Myelofibrosis, focal																	3			
MESENTERY/ABDOMINAL CAVITY																				
Lipogranuloma/fat necrosis																				
CLITORAL GLAND																				
Carcinoma																				
Adenoma																				
LYMPH NODE(S), NOS																				
Malignant lymphoma																				
Angiectasis, focal																				
HARDERIAN GLAND																				
Dacryoadenitis, unilateral																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND	L	L		L	L				L						L			L		L
Carcinoma																		P		
Adenoma																				
Fibroadenoma	P	P			P										P					P
Galactoceles															P					P
Cystic hyperplasia				3					1											
BONE MARROW									N											
Myelofibrosis, focal																				
MESENTERY/ABDOMINAL CAVITY	L													L						L
Lipogranuloma/fat necrosis	P													P						P
CLITORAL GLAND																L				
Carcinoma																P				
Adenoma																				
LYMPH NODE(S), NOS																				
Malignant lymphoma																				
Angiectasis, focal																				
HARDERIAN GLAND										L										
Dacryoadenitis, unilateral										2										

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MAMMARY GLAND							L	L	L		L		L	L								
Carcinoma																					1/15	0/6
Adenoma							P														0/15	1/6
Fibroadenoma								P						P							11/15	2/6
Galactoceles							P	P	P												5/15	3/6
Cystic hyperplasia											3		1								2/15	2/6
BONE MARROW		N		I																		
Myelofibrosis, focal																					1/3	-
MESENTERY/ABDOMINAL CAVITY																						
Lipogranuloma/fat necrosis																					3/3	-
CLITORAL GLAND								L														
Carcinoma																					1/1	0/1
Adenoma								P													0/1	1/1
LYMPH NODE(S), NOS						L					L											
Malignant lymphoma						P					P										-	2/2
Angiectasis, focal						3															-	1/2
HARDERIAN GLAND																						
Dacryoadenitis, unilateral																					1/1	-

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FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYMUS																				
Malignant lymphoma																				
FEMUR/VERTEBRAE																	N			

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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FINAL REPORT
F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
THYMUS																				
Malignant lymphoma																				
FEMUR/VERTEBRAE									N								N			

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**	TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																
BY PROTOCOL FOR THIS GROUP (continued)																
THYMUS						L										
Malignant lymphoma						P									-	1/1
FEMUR/VERTEBRAE		N														

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Astrocytoma																				
Leukemic infiltrates, monocytic																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	N	L	L	L	L	L	N	L	L	L	L	L	L	N	L	L
Adenoma		P	P	P				P	P	P		P	P	P	P	P	P		P	P
Carcinoma							P													
Leukemic infiltrates, monocytic																				
Cyst	P	P	P	P		P		P		P				P	P		P		P	
Hyperplasia, chromophobe-cell	1																			
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, monocytic	P						P						P			P				P
Focus of hyperplasia with cystic degeneration											P									

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Astrocytoma																				
Leukemic infiltrates, monocytic																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Adenoma	P	P	P	P	P	P	P	P		P	P	P	P		P	P	P	P	P	P
Carcinoma														P						
Leukemic infiltrates, monocytic																			P	
Cyst				P		P		P	P			P					P	P		
Hyperplasia, chromophobe-cell																				
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, monocytic					P			P											P	
Focus of hyperplasia with cystic degeneration			P																	

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N							
Astrocytoma													P								0/41	1/14
Leukemic infiltrates, monocytic													P								0/41	1/14
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N							
Leukemic infiltrates, monocytic													P								0/41	1/14
Hemorrhage, focal													3								0/41	1/14
PITUITARY	N	L	L	N	L	L	L	L	L	L	L	L	L	L	L							
Adenoma		P	P		P		P	P		P	P	P	P	P	P						32/41	11/14
Carcinoma																					2/41	0/14
Leukemic infiltrates, monocytic						P		P			P		P								1/41	4/14
Cyst									P	P	P		P		P						18/41	5/14
Hyperplasia, chromophobe-cell						1															1/41	1/14
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Leukemic infiltrates, monocytic	P	P			P	P		P	P	P	P	P	P								9/41	9/14
Focus of hyperplasia with cystic degeneration																					2/41	0/14

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
LIVER (continued)																				
Area(s) of hyperplasia with cystic																				
degeneration							P			P	P									
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P	P	P	P
Foci of cellular alteration-eosinophilic		P																		
Foci of cellular alteration-clear cells			P												P					
Area of cellular alteration-clear cells				P							P								P	
Foci of cellular alteration-mixed cells									P											
Hyperplasia, regenerative, focal																				
Necrosis, random, focal																1				
Necrosis, agonal, centrilobular																				
focal/multifocal/diffuse																				
Bile duct proliferation, focal/																				
multifocal/diffuse	2		2	1				1	1	1		1			1			1	1	
Cholangiofibrosis, focal/multifocal												1							1	
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse																				

continued next page

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
LIVER (continued)																				
Area(s) of hyperplasia with cystic degeneration										P		P		P					P	
Foci of cellular alteration-basophilic	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic				P				P							P					
Foci of cellular alteration-clear cells																P				
Area of cellular alteration-clear cells	P	P																		
Foci of cellular alteration-mixed cells																				
Hyperplasia, regenerative, focal							3													
Necrosis, random, focal																				
Necrosis, agonal, centrilobular focal/multifocal/diffuse																				
Bile duct proliferation, focal/ multifocal/diffuse	1	1	1	1	1			2			1	2		1	1		1	1	1	1
Cholangiofibrosis, focal/multifocal				1				1												
Metamorphosis, fatty, periportal/ centrilobular/random, focal/ multifocal/diffuse																				

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TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Area(s) of hyperplasia with cystic																						
degeneration																					7/41	0/14
Foci of cellular alteration-basophilic	P		P	P	P		P			P		P		P							40/41	7/14
Foci of cellular alteration-eosinophilic																					4/41	0/14
Foci of cellular alteration-clear cells																					3/41	0/14
Area of cellular alteration-clear cells																					5/41	0/14
Foci of cellular alteration-mixed cells																					1/41	0/14
Hyperplasia, regenerative, focal																					1/41	0/14
Necrosis, random, focal																					1/41	0/14
Necrosis, agonal, centrilobular																						
focal/multifocal/diffuse										2					2						0/41	2/14
Bile duct proliferation, focal/																						
multifocal/diffuse	2	2			1	2		2	2		1		2		1						25/41	8/14
Cholangiofibrosis, focal/multifocal	1							1	2				2								5/41	3/14
Metamorphosis, fatty, periportal/																						
centrilobular/random, focal/																						
multifocal/diffuse		4							2	2	3										0/41	4/14

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FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
LIVER (continued)																				
Extramedullary hematopoiesis, focal/ multifocal																				
Microgranulomas, focal/multifocal				2	1					1			1	2	1			1	1	
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, monocytic, unilateral/bilateral																P				
Nephropathy, chronic, unilateral/ bilateral	1	1	1	1	1	1	1	1	2	1	1	1	2	1	1	1	1	1	1	1
Inflammation, lymphocytic, unilateral/ bilateral						1	1		1	1		1	1						1	
Microconcretions, tubular, unilateral/ bilateral												1				1				
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets, bilateral																2		1		
Cortex, cyst, unilateral													P							
Bacteremia, bilateral																				

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2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDME = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
LIVER (continued)																				
Extramedullary hematopoiesis, focal/ multifocal																				
Microgranulomas, focal/multifocal	1		1			3			1		1				1	2	1			1
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, monocytic, unilateral/bilateral					P															
Nephropathy, chronic, unilateral/ bilateral	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	3
Inflammation, lymphocytic, unilateral/ bilateral	1			1			1							1		1			1	2
Microconcretions, tubular, unilateral/ bilateral																				
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets, bilateral																				
Cortex, cyst, unilateral																				
Bacteremia, bilateral																				

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
LIVER (continued)																						
Extramedullary hematopoiesis, focal/																						
multifocal															1						0/41	1/14
Microgranulomas, focal/multifocal												1									17/41	1/14
KIDNEY	LL	LL	LL	LL	LL	LL	NN	LL	LL	LL	LL	LL	LL	LL	NN							
Leukemic infiltrates, monocytic,																						
unilateral/bilateral		P				P		P			P		P								2/41	5/14
Nephropathy, chronic, unilateral/																						
bilateral	1	1	1	1	1			1	1	1		1	1	1							41/41	10/14
Inflammation, lymphocytic, unilateral/																						
bilateral														1							14/41	1/14
Microconcretions, tubular, unilateral/																						
bilateral								1													2/41	1/14
Cortex, increased pigment, bilateral									2	2											0/41	2/14
Cortex, protein resorption droplets,																						
bilateral												1									2/41	1/14
Cortex, cyst, unilateral																					1/41	0/14
Bacteremia, bilateral						P															0/41	1/14

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
HEART	L	L	L	L	L		L	L	L	L	L	L	L	L	L	L	L	L	L	L
Leukemic infiltrates, monocytic	P						P									P				
Myocarditis, chronic, focal/multifocal	1	1	1	1	1	1	1	2	2	1	2	1	1	1	1		1	1	2	1
SPLEEN	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L	N	L	L	L
Monocytic leukemia	P						P					P	P			P				P
Congestion, diffuse																			1	
Increased extramedullary hematopoiesis								1				1	1	2				1		
Increased pigment, diffuse		2	2	1		1		2	2	2	2				2			2	2	
Infarction, focal																				
Fibrosis, focal/multifocal							2													
OVARY	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NL	NN	NN	NN	NN	NL
Leukemic infiltrates, monocytic, unilateral/bilateral																				
Cyst(s), follicular, unilateral/bilateral		P													P					
Hematocysts, unilateral																				P

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
HEART	L	L	L	N	N	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	1	1	1			1	2	1	2	1	1	1	2	1	2	1	1		1	1
SPLEEN	L	L	L	L	L	N	L	L	L	L	L	L	L	L	N	L	L	L	L	L
Monocytic leukemia					P			P											P	
Congestion, diffuse																2				
Increased extramedullary hematopoiesis	1	1	1						2		1						1			
Increased pigment, diffuse	2	2	2	2			2		1	2	2	1	2	2		1	2	2		2
Infarction, focal																				
Fibrosis, focal/multifocal																				
OVARY	NN	NN	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cyst(s), follicular, unilateral/																				
bilateral				P																
Hematocysts, unilateral																				

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
HEART	L	L	L	L	L	L	L	L	N	L	L	L	L	L	N							
Leukemic infiltrates, monocytic		P				P					P		P								3/41	4/14
Myocarditis, chronic, focal/multifocal	1	1	2	1	1	1	1	1		1		1		2							37/41	10/14
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L							
Monocytic leukemia	P	P			P	P		P	P	P	P	P	P								10/41	9/14
Congestion, diffuse																					2/41	0/14
Increased extramedullary hematopoiesis			2	2										1							11/41	3/14
Increased pigment, diffuse							2					3		2	2						26/41	4/14
Infarction, focal		2											3								0/41	2/14
Fibrosis, focal/multifocal															2						1/41	1/14
OVARY	NN	NN	NN	NN	NN	NN	NN	NM	NN	NN	NN	NN	LL	NN	NM							
Leukemic infiltrates, monocytic, unilateral/bilateral													P								0/41	1/14
Cyst(s), follicular, unilateral/ bilateral																					3/41	0/14
Hematocysts, unilateral																					1/41	0/14

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE																				
Phthisis bulbi, unilateral																				
ADRENAL														L						
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cortex, angiectasis, unilateral/																				
bilateral														3						
PANCREAS				N																
Leukemic infiltrates, monocytic																				
MESENTERIC LYMPH NODE																				
Monocytic leukemia																				
Reticular cell hyperplasia																				
UTERUS		L		L		L	L							L						
Adenocarcinoma, endometrial		P																		
Endometrial stromal sarcoma																				
Endometrial stromal polyp				P		P	P							P						
Cyst, endometrial																				
Luminal dilatation-hydrometra																				

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[illegible] = [illegible] minimal [illegible] = [illegible] spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP																				
EYE						N							N						L	
Phthisis bulbi, unilateral																			P	
ADRENAL																				
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Cortex, angiectasis, unilateral/																				
bilateral																				
PANCREAS																				
Leukemic infiltrates, monocytic																				
MESENTERIC LYMPH NODE															L					
Monocytic leukemia																				
Reticular cell hyperplasia															2					
UTERUS	L					L	L					L					L	L	L	L
Adenocarcinoma, endometrial																				
Endometrial stromal sarcoma																				
Endometrial stromal polyp	P					P						P							P	
Cyst, endometrial							P											P		P
Luminal dilatation-hydrometra												P					P	P		

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP																						
EYE																						
Phthisis bulbi, unilateral																					1/3	-
ADRENAL													L									
Leukemic infiltrates, monocytic, unilateral/bilateral													P								0/1	1/1
Cortex, angiectasis, unilateral/bilateral																					1/1	0/1
PANCREAS								L					N									
Leukemic infiltrates, monocytic								P													0/1	1/2
MESENTERIC LYMPH NODE		L				L					L		L									
Monocytic leukemia		P				P					P		P								0/1	4/4
Reticular cell hyperplasia																					1/1	0/4
UTERUS			L	L	L		N	L					L	L								
Adenocarcinoma, endometrial																					1/13	0/7
Endometrial stromal sarcoma			P	P				P													0/13	3/7
Endometrial stromal polyp					P																8/13	1/7
Cyst, endometrial													P	P							3/13	2/7
Luminal dilatation-hydrometra																					3/13	0/7

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
URINARY BLADDER																				
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI														L						
Bronchiolar-alveolar adenoma																				
Leukemic infiltrates, monocytic																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal														1						
THYROID														L						
C-cell carcinoma, unilateral														P						
STOMACH																				
Mucosal ulcer, glandular region																				
DUODENUM																				
JEJUNUM																				
CECUM																				
SKIN								N				N				L				
Basal cell tumor																P				
Malignant fibrous histiocytoma																				

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FINAL REPORT
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
URINARY BLADDER																				
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI																		L		
Bronchiolar-alveolar adenoma																		P		
Leukemic infiltrates, monocytic																				
Lymphoid infiltrates,																				
peribronchial/iolar, focal																		2		
THYROID																				
C-cell carcinoma, unilateral																				
STOMACH																				
Mucosal ulcer, glandular region																				
DUODENUM																				
JEJUNUM																				
CECUM																				
SKIN															N					
Basal cell tumor																				
Malignant fibrous histiocytoma																				

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F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
URINARY BLADDER				N				L														
Leukemic infiltrates, monocytic								P													-	1/2
LUNG-MAINSTEM BRONCHI			L		L	L	L	L	L			L	L									
Bronchiolar-alveolar adenoma																					1/2	0/8
Leukemic infiltrates, monocytic						P		P	P				P								0/2	4/8
Lymphoid infiltrates,																						
peribronchial/iolar, focal			2		1		2					1									2/2	4/8
THYROID																						
C-cell carcinoma, unilateral																					1/1	-
STOMACH				L																		
Mucosal ulcer, glandular region				2																	-	1/1
DUODENUM						I																
JEJUNUM						I																
CECUM						I																
SKIN		N			L				N			N	N									
Basal cell tumor																					1/4	0/5
Malignant fibrous histiocytoma					P																0/4	1/5

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F344 Female Rats
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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND	L									L					L	L	L	L		
Carcinoma																P				
Fibroadenoma	P																P	P		
Galactoceles										P					P		P			
Cystic hyperplasia																				
MESENTERY/ABDOMINAL CAVITY			L													L				
Lipogranuloma/fat necrosis			P													P				
CLITORAL GLAND																				
Carcinoma																				
LYMPH NODE(S), NOS				N																
Monocytic leukemia																				
Angiectasis, focal																				
SALIVARY GLAND																				
HARDERIAN GLAND																				
Leukemic infiltrates, monocytic																				
MUSCLE, NOS																				
LARYNX																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR THIS GROUP (continued)																				
MAMMARY GLAND				L	L			L	L	L					L					
Carcinoma																				
Fibroadenoma								P	P						P					
Galactoceles				P	P				P	P										
Cystic hyperplasia					3															
MESENTERY/ABDOMINAL CAVITY		L										L					L			
Lipogranuloma/fat necrosis		P										P					P			
CLITORAL GLAND														L						
Carcinoma														P						
LYMPH NODE(S), NOS																				
Monocytic leukemia																				
Angiectasis, focal																				
SALIVARY GLAND																				
HARDERIAN GLAND																			L	
Leukemic infiltrates, monocytic																			P	
MUSCLE, NOS				N																
LARYNX																				

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F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR THIS GROUP (continued)																						
MAMMARY GLAND					L				L					L								
Carcinoma																					1/12	0/3
Fibroadenoma					P									P							6/12	2/3
Galactoceles																					7/12	0/3
Cystic hyperplasia									2												1/12	1/3
MESENTERY/ABDOMINAL CAVITY										L												
Lipogranuloma/fat necrosis										P											5/5	1/1
CLITORAL GLAND																						
Carcinoma																					1/1	-
LYMPH NODE(S), NOS				N		L		L		L	L		L		N							
Monocytic leukemia						P		P		P	P		P								0/1	5/7
Angiectasis, focal										2											0/1	1/7
SALIVARY GLAND				N				N														
HARDERIAN GLAND																						
Leukemic infiltrates, monocytic																					1/1	-
MUSCLE, NOS																						
LARYNX							N															

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
Cerebrum, mineralized foci																				
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Hemorrhage, focal																				
PITUITARY	L	L	N	L	L	L	L	M	L	L	L	L	N	L	L	L	L	L	L	L
Adenoma		P			P					P					P	P	P		P	P
Carcinoma	P																			
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
Cyst				P	P				P		P	P		P			P	P	P	
Hyperplasia, chromophobe-cell						2	2											1		
EYE	LL	LL	NL	LL	LL	LL	NL	LL	LL	LL	LL	NL	NN	NL	LL	LL	NN	LL	NL	NN
Leukemic infiltrates, lymphocytic				P																

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
BRAIN	N	N	N	N	N	N	N	N	N	N	N	N	L	L	L	N	N	N	N	N
Leukemic infiltrates, lymphocytic															P					
Leukemic infiltrates, monocytic													P							
Hemorrhage, focal													3		1					
Cerebrum, mineralized foci														P						
SPINAL CORD	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic													P							
Hemorrhage, focal													3							
PITUITARY	L	L	L	L	L	N	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Adenoma	P	P	P	P	P		P	P	P			P					P	P		P
Carcinoma																				
Leukemic infiltrates, lymphocytic										P					P					
Leukemic infiltrates, monocytic									P			P	P			P			P	
Cyst					P		P	P		P				P	P				P	
Hyperplasia, chromophobe-cell											2			1						
EYE	LL	LL	LL	LL	LL	NL	NN	NN	NN	NN	NL	NN	NN	NL	NN	NN	NN	NL	NN	LL
Leukemic infiltrates, lymphocytic																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] term[illegible] sac[illegible] [illegible] DMS — [illegible]ntaneous death/moribund sacrifice

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
BRAIN	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic									0/28	1/20
Leukemic infiltrates, monocytic									0/28	1/20
Hemorrhage, focal									0/28	2/20
Cerebrum, mineralized foci									0/28	1/20
SPINAL CORD	N	N	N	N	N	N	N	N		
Leukemic infiltrates, monocytic									0/28	1/20
Hemorrhage, focal									0/28	1/20
PITUITARY	M	L	L	L	L	L	L	L		
Adenoma		P	P		P	P	P		15/27	10/19
Carcinoma				P					1/27	1/19
Leukemic infiltrates, lymphocytic		P							1/27	3/19
Leukemic infiltrates, monocytic									0/27	5/19
Cyst		P	P					P	12/27	7/19
Hyperplasia, chromophobe-cell									3/27	2/19
EYE	LM	LL	NL	NN	NN	NL	LM	NL		
Leukemic infiltrates, lymphocytic									1/28	0/20

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
EYE (continued)																				
Keratitis, chronic, unilateral, focal/multifocal/diffuse											2							3		
Lens, cataract, unilateral/bilateral	P	P	P	P	P	P	P	P	P	P	P	P		P	P	P		P	P	
Lens-induced inflammation, unilateral/bilateral					P	P					P				P	P		P		
Degeneration, retinal, unilateral/bilateral		2	2	3	3	2		3	2					2						
Phthisis bulbi, unilateral															P					
OPTIC NERVE	NN	NN	NN	NN	NN	NN	NN	NN	NN	NM	NN	NN	NN	NM	NM	NN	NN	NN	NN	NN
ADRENAL	NN	NL	LL	LL	NL	LL	LL	NN	NL	NN	LL	LL	NL	LL	NN	LL	NL	LL	NN	LL
Pheochromocytoma, unilateral													P							
Leukemic infiltrates, lymphocytic, bilateral				P																
Leukemic infiltrates, monocytic, unilateral/bilateral																				
Cortex, cytomegally, focal, unilateral																	2			
Cortex, hyperplasia, focal, unilateral									1											

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T = terminal sacrifice MS = moribund death

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
EYE (continued)																				
Keratitis, chronic, unilateral, focal/multifocal/diffuse	2		2	1		4														2
Lens, cataract, unilateral/bilateral	P	P	P	P	P	P					P			P				P		P
Lens-induced inflammation, unilateral/bilateral		P	P	P										P						
Degeneration, retinal, unilateral/bilateral	2				2															
Phthisis bulbi, unilateral																				
OPTIC NERVE	NN	NN	NN	NN	NN	NM	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NM
ADRENAL	NL	NL	NN	LL	NL	LL	NN	NN	LL	NN	LL	LL	LL	LL	NN	NN	LL	LL	LL	NL
Pheochromocytoma, unilateral		P										P								
Leukemic infiltrates, lymphocytic, bilateral											P									
Leukemic infiltrates, monocytic, unilateral/bilateral				P					P			P	P						P	
Cortex, cytomegally, focal, unilateral																				
Cortex, hyperplasia, focal, unilateral																		2		

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ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SOMS Incidence
EYE (continued)										
Keratitis, chronic, unilateral, focal/multifocal/diffuse			3						6/28	2/20
Lens, cataract, unilateral/bilateral	P	P				P	P	P	23/28	9/20
Lens-induced inflammation, unilateral/bilateral							P		9/28	2/20
Degeneration, retinal, unilateral/bilateral	2							2	10/28	2/20
Phthisis bulbi, unilateral									1/28	0/20
OPTIC NERVE	NM	NN	NN	NN	NN	NN	NN	NN		
ADRENAL	NL	LL	LL	NN	NN	NN	LL	LL		
Pheochromocytoma, unilateral			P						2/28	2/20
Leukemic infiltrates, lymphocytic, bilateral		P							1/28	2/20
Leukemic infiltrates, monocytic, unilateral/bilateral									1/28	4/20
Cortex, cytomegally, focal, unilateral									1/28	0/20
Cortex, hyperplasia, focal, unilateral									1/28	1/20

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ORGAN Lesion / Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
ADRENAL (continued)																				
Cortex, metamorphosis, fatty,																				
unilateral/bilateral		1	1																	
Cortex, angiectasis, unilateral/																				
bilateral			2		1	1	1				1	2		1		1	1	1		2
Medulla, hyperplasia, focal, unilateral																				2
SPLEEN	L	L	N	L	L	L	L	L	L	L	L	L	N	L	N	L	L	L	L	L
Malignant lymphoma				P								P								
Monocytic leukemia	P					P	P				P			P				P	P	P
Congestion, diffuse								2									2			
Increased extramedullary hematopoiesis																				
Increased pigment, diffuse		2			1			2	1	2						2	2			
Infarction, focal																				
PANCREAS	N	N	N	L	N	L	N	N	L	N	L	N	N	N	N	N	N	N	N	N
Islet cell adenoma																				
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
Hyperplasia, islet cell, focal																				

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ORGAN Lesion / Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
ADRENAL (continued)																				
Cortex, metamorphosis, fatty, unilateral/bilateral	1			2	1	1												1		
Cortex, angiectasis, unilateral/bilateral														2			1		1	1
Medulla, hyperplasia, focal, unilateral																				
SPLEEN	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L	N
Malignant lymphoma										P	P				P					
Monocytic leukemia			P	P			P		P			P	P	P		P	P		P	
Congestion, diffuse		2			1	1		2												
Increased extramedullary hematopoiesis	2																1			
Increased pigment, diffuse		2			1			2												
Infarction, focal												3								
PANCREAS	L	N	N	N	N	N	N	N	L	L	L	L	N	N	L	L	L	L	N	N
Islet cell adenoma																		P		
Leukemic infiltrates, lymphocytic										P	P				P					
Leukemic infiltrates, monocytic									P			P				P				
Hyperplasia, islet cell, focal																	1			

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
ADRENAL (continued)										
Cortex, metamorphosis, fatty,										
unilateral/bilateral	1	2					1	3	6/28	5/20
Cortex, angiectasis, unilateral/										
bilateral			1						11/28	5/20
Medulla, hyperplasia, focal, unilateral									1/28	0/20
SPLEEN	L	L	L	L	L	L	L	L		
Malignant lymphoma		P							2/28	4/20
Monocytic leukemia	P							P	11/28	9/20
Congestion, diffuse									6/28	0/20
Increased extramedullary hematopoiesis			1	1	3	2			1/28	5/20
Increased pigment, diffuse				1			3		10/28	2/20
Infarction, focal									0/28	1/20
PANCREAS	L	L	L	N	N	N	N	N		
Islet cell adenoma	P								0/28	2/20
Leukemic infiltrates, lymphocytic		P							1/28	4/20
Leukemic infiltrates, monocytic									0/28	3/20
Hyperplasia, islet cell, focal									0/28	1/20

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PANCREAS (continued)																				
Atrophy, acinar cell, focal/multifocal						1			1		1									
MESENTERIC LYMPH NODE	N	N	N	L	N	L	N	N	N	N	N	L	N	N	N	N	N	N	N	N
Monocytic leukemia						P														
Malignant lymphoma				P								P								
Angiectasis, multifocal																				
OVARY	NN	NN	NN	LL	NN	NN	NN	NN	NN	NN	NL	LL	NN	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic, unilateral/bilateral				P								P								
Leukemic infiltrates, monocytic, unilateral/bilateral											P									
Cyst(s), follicular, unilateral/bilateral																				
UTERUS	N	N	L	L	N	L	L	N	N	N	L	N	L	N	N	N	L	N	L	L
Endometrial stromal polyp			P								P		P				P		P	P
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				

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ORGAN / Lesion — Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
PANCREAS (continued)																				
Atrophy, acinar cell, focal/multifocal	1																			
MESENTERIC LYMPH NODE	N	N	N	N	N	N	N	N	L	L	L	L	L	N	L	L	N	N	L	N
Monocytic leukemia									P			P	P			P			P	
Malignant lymphoma										P	P				P					
Angiectasis, multifocal									3											
OVARY	NN	NN	NN	NN	NN	NN	NN	NN	NN	LL	NL	NN	LM	NN	NN	NN	NN	NN	LL	NN
Leukemic infiltrates, lymphocytic, unilateral/bilateral										P										
Leukemic infiltrates, monocytic, unilateral/bilateral													P						P	
Cyst(s), follicular, unilateral/bilateral											P								P	
UTERUS	L	L	L	L	N	L	L	N	L	N	N	L	L	L	N	L	L	L	L	N
Endometrial stromal polyp	P	P	P				P		P				P				P	P	P	
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic									P			P	P			P				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
PANCREAS (continued)										
Atrophy, acinar cell, focal/multifocal			1						4/28	1/20
MESENTERIC LYMPH NODE	M	L	N	N	N	M	N	N		
Monocytic leukemia									1/28	5/18
Malignant lymphoma		P							2/28	4/18
Angiectasis, multifocal									0/28	1/18
OVARY	NN	NN	NN	NN	NN	NN	NN	NN		
Leukemic infiltrates, lymphocytic, unilateral/bilateral									2/28	1/20
Leukemic infiltrates, monocytic, unilateral/bilateral									1/28	2/20
Cyst(s), follicular, unilateral/bilateral									0/28	2/20
UTERUS	L	N	N	N	N	N	N	N		
Endometrial stromal polyp	P								10/28	6/20
Leukemic infiltrates, lymphocytic									1/28	0/20
Leukemic infiltrates, monocytic									0/28	4/20

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ORGAN Lesion / Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
UTERUS (continued)																				
Hyperplasia, endometrial			3				2													
Cyst, endometrial						P					P		P							P
Luminal dilatation-hydrometra																				
Luminal dilatation-hemorrhage																				
URINARY BLADDER	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Papilloma																				
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Carcinoma, metastatic, mammary																				
Carcinoma, metastatic, squamous cell																				
Leukemic infiltrates, lymphocytic				P								P								
Leukemic infiltrates, monocytic						P	P												P	P
Alveolar macrophages, focal/multifocal					1	1			2				1				1			
Lymphoid infiltrates,																				
peribronchial/iolar, focal	2	2	2		2	1	2	2	2	1	1	1	1	2	1	2	2	1	2	2
Bronchopneumonia, focal																				

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UTERUS (continued)																				
Hyperplasia, endometrial																				
Cyst, endometrial	P		P			P								P			P			
Luminal dilatation-hydrometra									P										P	
Luminal dilatation-hemorrhage				P																
URINARY BLADDER	N	N	L	N	N	N	N	N	N	L	N	L	N	N	N	L	N	N	N	N
Papilloma			P																	
Leukemic infiltrates, lymphocytic										P										
Leukemic infiltrates, monocytic												P				P				
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L	L	L	L	L	L	N	L	L	L	L	L	L
Carcinoma, metastatic, mammary																				
Carcinoma, metastatic, squamous cell																				
Leukemic infiltrates, lymphocytic										P	P				P					
Leukemic infiltrates, monocytic				P					P			P	P			P	P		P	
Alveolar macrophages, focal/multifocal																		1		
Lymphoid infiltrates,																				
peribronchial/iolar, focal	2	2	1	1	2	2	2	1								2	1	1		2
Bronchopneumonia, focal																				1

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UTERUS (continued)										
Hyperplasia, endometrial									2/28	0/20
Cyst, endometrial									7/28	2/20
Luminal dilatation-hydrometra									0/28	2/20
Luminal dilatation-hemorrhage									1/28	0/20
URINARY BLADDER	N	N	N	N	N	N	N	N		
Papilloma									1/28	0/20
Leukemic infiltrates, lymphocytic									1/28	1/20
Leukemic infiltrates, monocytic									0/28	2/20
LUNG-MAINSTEM BRONCHI	L	L	L	L	L	L	L	L		
Carcinoma, metastatic, mammary					P				0/28	1/20
Carcinoma, metastatic, squamous cell			P						0/28	1/20
Leukemic infiltrates, lymphocytic		P							2/28	4/20
Leukemic infiltrates, monocytic	P							P	5/28	8/20
Alveolar macrophages, focal/multifocal									5/28	1/20
Lymphoid infiltrates,										
peribronchial/iolar, focal	1	1	1	1	2	2	1	1	27/28	12/20
Bronchopneumonia, focal									0/28	1/20

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LUNG-MAINSTEM BRONCHI (continued)																				
Congestion, agonal, diffuse																2				
Alveolar septae, fibrinoid degeneration, focal																				
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	N	L	N	L	N	L	L	L	L	N	L	L	L	N	N	L	L	N	N	L
Leukemic infiltrates, lymphocytic																				
Inflammation, chronic		1		2		1	2	2	1		2	1	1			2	1			1
Mucocele(s), submucosal, focal													2							
THYROID	LL	NN	NN	NN	NN	NN	NL	NL	NN	NN	NL	NN	NN	NL	NL	LL	NL	NL	LL	NL
C-cell adenoma, unilateral/bilateral	P						P	P							P		P			
Follicular cystadenoma, unilateral																			P	
Hyperplasia, C-cell, unilateral/ bilateral, focal								1			1			1		1			2	1
Cystic follicle(s), unilateral/ bilateral																		P		

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TS [illegible] = [illegible] aneo[illegible]ath/[illegible]bund [illegible]ific

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
LUNG-MAINSTEM BRONCHI (continued)																				
Congestion, agonal, diffuse		1																2		
Alveolar septae, fibrinoid degeneration, focal																				
ESOPHAGUS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
TRACHEA	N	N	L	L	L	N	L	N	N	L	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic										P										
Inflammation, chronic			2	1	2		2													
Mucocele(s), submucosal, focal																				
THYROID	NL	NL	NL	NN	NN	NN	NL	NL	NN	NN	NN	NN	NL	NN	NN	NN	LL	NL	NL	NL
C-cell adenoma, unilateral/bilateral																	P	P		P
Follicular cystadenoma, unilateral																				
Hyperplasia, C-cell, unilateral/ bilateral, focal		1																	1	
Cystic follicle(s), unilateral/ bilateral	P		P				P	P					P				P			

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
LUNG-MAINSTEM BRONCHI (continued)										
Congestion, agonal, diffuse				2					2/28	2/20
Alveolar septae, fibrinoid degeneration, focal		2							0/28	1/20
ESOPHAGUS	N	N	N	N	N	N	N	N		
TRACHEA	N	L	N	N	L	N	N	N		
Leukemic infiltrates, lymphocytic									0/28	1/20
Inflammation, chronic		2			1				16/28	2/20
Mucocele(s), submucosal, focal		1							1/28	1/20
THYROID	LL	LL	LL	NL	LL	NL	NL	LL		
C-cell adenoma, unilateral/bilateral						P		P	5/28	5/20
Follicular cystadenoma, unilateral									1/28	0/20
Hyperplasia, C-cell, unilateral/bilateral, focal		1	1	1	1		1	1	7/28	7/20
Cystic follicle(s), unilateral/bilateral	P	P							5/28	4/20

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
PARATHYROID	NN	NN	NN	NN	NM	NN	NN	NM	NM	NN	NM	NN	NM	NN	NN	NM	NM	NN	NN	NN
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neurilemmoma															P					
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
Myocarditis, chronic, focal/multifocal	2	2	2		1	1	1	1	1	1	1	1	1	2		1	2	1	1	1
Auricular thrombosis																				
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule	P																	P		
Malignant fibrous histiocytoma																				
Leukemic infiltrates, lymphocytic				P								P								
Leukemic infiltrates, monocytic	P					P	P				P			P				P	P	P
Foci of cellular alteration-basophilic	P	P	P		P			P		P	P	P	P	P	P	P	P	P	P	P
Foci of cellular alteration-eosinophilic					P										P					P
Area of cellular alteration-clear cells													P	P						P
Foci of cellular alteration-mixed cells												P				P				
Hyperplasia, regenerative, focal																				
Necrosis, random, focal																				

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
PARATHYROID	NN	NN	NN	NN	NN	NM	NN	NN	NN	NM	NN	NM	NN	NN	NM	NM	NN	NM	NN	NN
HEART	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neurilemmoma																				
Leukemic infiltrates, lymphocytic										P	P				P					
Leukemic infiltrates, monocytic				P					P			P	P			P			P	
Myocarditis, chronic, focal/multifocal	2	2	2	1	2	2	1	1				1		1			1	2	1	1
Auricular thrombosis				P							P									
LIVER	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L
Neoplastic nodule					P							P								
Malignant fibrous histiocytoma																				P
Leukemic infiltrates, lymphocytic										P	P				P					
Leukemic infiltrates, monocytic			P	P			P		P			P	P	P		P	P		P	
Foci of cellular alteration-basophilic	P		P	P	P	P	P	P					P				P	P		
Foci of cellular alteration-eosinophilic																				
Area of cellular alteration-clear cells						P	P													
Foci of cellular alteration-mixed cells			P			P														
Hyperplasia, regenerative, focal		3																		
Necrosis, random, focal												3								

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] terminal sacrifice [illegible] SDMS [illegible] spontaneous death/moribund sacrifice

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
PARATHYROID	NN	NN	NN	NN	MM	NN	NN	NM		
HEART	N	L	L	L	N	L	N	L		
Neurilemmoma									1/28	0/20
Leukemic infiltrates, lymphocytic									1/28	3/20
Leukemic infiltrates, monocytic									1/28	5/20
Myocarditis, chronic, focal/multifocal		1	1	1		1		1	26/28	11/20
Auricular thrombosis								P	1/28	2/20
LIVER	L	L	L	L	L	L	L	L		
Neoplastic nodule									3/28	1/20
Malignant fibrous histiocytoma									0/28	1/20
Leukemic infiltrates, lymphocytic		P							2/28	4/20
Leukemic infiltrates, monocytic	P							P	11/28	9/20
Foci of cellular alteration-basophilic			P	P	P	P	P		23/28	8/20
Foci of cellular alteration-eosinophilic				P					3/28	1/20
Area of cellular alteration-clear cells									5/28	0/20
Foci of cellular alteration-mixed cells									4/28	0/20
Hyperplasia, regenerative, focal									1/28	0/20
Necrosis, random, focal									0/28	1/20

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LIVER (continued)																				
Bile duct proliferation, focal/																				
multifocal		1		2																
Cholangiofibrosis, focal/multifocal																				
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse				2																
Microgranulomas, focal/multifocal								1	1				1	2						
Mononuclear cell infiltrates,																				
sinusoidal, diffuse			2																	
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral				P								P								
Leukemic infiltrates, monocytic,																				
unilateral/bilateral																				
Nephropathy, chronic, unilateral/																				
bilateral	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1
Inflammation, lymphocytic, unilateral/																				
bilateral			1		1								1	1	1	1	1		1	

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ORGAN Lesion / Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
LIVER (continued)																				
Bile duct proliferation, focal/																				
multifocal				2				1	3		3	2	2	2		1	2		2	
Cholangiofibrosis, focal/multifocal											2			2						
Metamorphosis, fatty, periportal/																				
centrilobular/random, focal/																				
multifocal/diffuse				3							3			2					2	
Microgranulomas, focal/multifocal																		2		
Mononuclear cell infiltrates,																				
sinusoidal, diffuse																				
KIDNEY	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL	LL
Leukemic infiltrates, lymphocytic,																				
unilateral/bilateral										P					P					
Leukemic infiltrates, monocytic,																				
unilateral/bilateral									P			P	P			P				
Nephropathy, chronic, unilateral/																				
bilateral	1	2	1	1	1	1	1	1	1	1	1	1	1	1		1	1	1	1	1
Inflammation, lymphocytic, unilateral/																				
bilateral		1					1	1												

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
LIVER (continued)										
Bile duct proliferation, focal/										
multifocal	2	3						2	4/28	11/20
Cholangiofibrosis, focal/multifocal		2							0/28	3/20
Metamorphosis, fatty, periportal/										
centrilobular/random, focal/										
multifocal/diffuse		3						3	2/28	5/20
Microgranulomas, focal/multifocal			1	1			1		4/28	4/20
Mononuclear cell infiltrates,										
sinusoidal, diffuse									1/28	0/20
KIDNEY	LL	LL	LL	LL	NL	LL	LL	LL		
Leukemic infiltrates, lymphocytic,										
unilateral/bilateral									2/28	2/20
Leukemic infiltrates, monocytic,										
unilateral/bilateral									0/28	4/20
Nephropathy, chronic, unilateral/										
bilateral	1	2	1	2	1	2	1	1	28/28	19/20
Inflammation, lymphocytic, unilateral/										
bilateral				1					11/28	1/20

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KIDNEY (continued)																				
Microconcretions, tubular, unilateral/																				
bilateral							1											1	1	
Cortex, increased pigment, bilateral																				
Cortex, protein resorption droplets,																				
bilateral				2																
Cortex, cyst, unilateral																				
Infarction, unilateral/bilateral, focal																				
STOMACH	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
Inflammation, forestomach																		2		
Mucosal ulcer, glandular region																				
Mucosal ulcer, forestomach																				
Mineralization, uremic																				
DUODENUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
JEJUNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

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KIDNEY (continued)																				
Microconcretions, tubular, unilateral/																				
bilateral							1						1				1	1		
Cortex, increased pigment, bilateral												3							2	
Cortex, protein resorption droplets,																				
bilateral																				
Cortex, cyst, unilateral		P																		
Infarction, unilateral/bilateral, focal																				
STOMACH	N	N	N	N	N	N	N	N	L	L	L	N	N	L	L	N	N	L	N	N
Leukemic infiltrates, lymphocytic										P										
Leukemic infiltrates, monocytic									P											
Inflammation, forestomach														2						
Mucosal ulcer, glandular region									3		2				2					
Mucosal ulcer, forestomach									2									3		
Mineralization, uremic																				
DUODENUM	N	N	N	N	N	N	N	N	N	I	N	N	N	N	N	N	N	N	N	N
JEJUNUM	N	N	N	N	N	N	N	N	N	I	N	N	N	N	N	N	N	N	N	N

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HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SOMS Incidence
KIDNEY (continued)										
Microconcretions, tubular, unilateral/										
bilateral			2				1		4/28	5/20
Cortex, increased pigment, bilateral									0/28	2/20
Cortex, protein resorption droplets,										
bilateral		2							1/28	1/20
Cortex, cyst, unilateral									1/28	0/20
Infarction, unilateral/bilateral, focal		2							0/28	1/20
STOMACH	L	L	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic									1/28	1/20
Leukemic infiltrates, monocytic									0/28	1/20
Inflammation, forestomach									1/28	1/20
Mucosal ulcer, glandular region	2								0/28	4/20
Mucosal ulcer, forestomach									0/28	2/20
Mineralization, uremic		1							0/28	1/20
DUODENUM	N	N	N	N	N	N	N	N		
JEJUNUM	N	N	N	N	N	N	N	N		

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ILEUM	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic				P																
CECUM	N	N	N	L	N	N	N	N	N	N	L	L	N	N	N	L	N	N	N	N
Leukemic infiltrates, monocytic																				
Nematode parasites in lumen				P							P	P				P				
Inflammation with ulceration																				
COLON	N	N	N	L	L	L	N	N	N	N	L	L	L	N	N	N	N	N	L	N
Leukemic infiltrates, monocytic																				
Nematode parasites in lumen				P	P	P					P	P	P						P	
RECTUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, monocytic																				
Nematode parasites in lumen																				
SKIN	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N	N	N	L	N	N
Squamous cell carcinoma																				
Malignant fibrous histiocytoma																		P		
Leukemic infiltrates, lymphocytic																				

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ILEUM	N	N	N	N	N	N	N	N	I	I	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
CECUM	N	L	N	N	N	N	N	N	L	I	L	L	N	N	N	L	N	N	N	N
Leukemic infiltrates, monocytic									P			P				P				
Nematode parasites in lumen		P									P									
Inflammation with ulceration									2											
COLON	N	N	N	N	N	N	N	N	N	I	L	L	N	N	N	L	N	N	L	N
Leukemic infiltrates, monocytic																P				
Nematode parasites in lumen											P	P							P	
RECTUM	L	N	N	N	N	N	N	L	N	I	N	N	N	N	N	L	N	N	N	N
Leukemic infiltrates, monocytic																P				
Nematode parasites in lumen	P							P												
SKIN	N	N	N	N	N	N	N	N	L	L	N	L	N	N	L	N	N	N	N	L
Squamous cell carcinoma																				
Malignant fibrous histiocytoma																				P
Leukemic infiltrates, lymphocytic										P										

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ILEUM	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic									1/28	0/18
CECUM	N	L	N	N	L	N	N	N		
Leukemic infiltrates, monocytic									0/28	3/19
Nematode parasites in lumen					P				5/28	2/19
Inflammation with ulceration		2							0/28	2/19
COLON	N	N	N	N	N	N	N	N		
Leukemic infiltrates, monocytic									0/28	1/19
Nematode parasites in lumen									7/28	3/19
RECTUM	N	N	N	N	N	N	N	N		
Leukemic infiltrates, monocytic									0/28	1/19
Nematode parasites in lumen									2/28	0/19
SKIN	N	N	L	N	N	N	N	L		
Squamous cell carcinoma			P						0/28	1/20
Malignant fibrous histiocytoma									1/28	1/20
Leukemic infiltrates, lymphocytic									0/28	1/20

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ORGAN / Lesion — Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
SKIN (continued)																				
Leukemic infiltrates, monocytic																				
Inflammation, dermal																				
Exudative crusts																				
Epidermal inclusion cyst													P							
Epidermal ulceration																				
MAMMARY GLAND	N	L	N	L	N	N	N	L	N	N	N	L	N	N	L	L	N	N	L	N
Carcinosarcoma																				
Fibroadenoma												P							P	
Galactoceles				P				P								P				
Cystic hyperplasia		2						2							2					
STERNUM	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Bone resorption and fibrosis, focal																				
BONE MARROW	N	N	N	L	L	N	L	L	L	N	N	N	L	N	N	N	L	N	N	L
Leukemic infiltrates, lymphocytic				P																
Leukemic infiltrates, monocytic																				
Myelofibrosis, focal					1		1	2	1				1				1			2

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

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L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN / Lesion — Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
SKIN (continued)																				
Leukemic infiltrates, monocytic									P											
Inflammation, dermal																				
Exudative crusts												P								
Epidermal inclusion cyst																				
Epidermal ulceration												P			P					
MAMMARY GLAND	N	L	N	N	N	N	N	N	N	N	N	M	N	N	N	N	N	L	M	M
Carcinosarcoma																				
Fibroadenoma																		P		
Galactoceles		P																		
Cystic hyperplasia		1																		
STERNUM	N	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N
Bone resorption and fibrosis, focal									2											
BONE MARROW	N	N	N	N	L	N	N	N	N	L	L	L	N	N	L	N	N	N	N	N
Leukemic infiltrates, lymphocytic										P	P				P					
Leukemic infiltrates, monocytic												P								
Myelofibrosis, focal					2															

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SDMS Incidence
SKIN (continued)										
Leukemic infiltrates, monocytic									0/28	1/20
Inflammation, dermal								P	0/28	1/20
Exudative crusts								P	0/28	2/20
Epidermal inclusion cyst									1/28	0/20
Epidermal ulceration									0/28	2/20
MAMMARY GLAND	N	N	N	L	L	L	L	N		
Carcinosarcoma					P				0/28	1/17
Fibroadenoma						P			2/28	2/17
Galactoceles				P			P		4/28	2/17
Cystic hyperplasia							2		4/28	1/17
STERNUM	N	N	N	N	N	N	N	N		
Bone resorption and fibrosis, focal									0/28	1/20
BONE MARROW	N	L	N	N	N	N	N	L		
Leukemic infiltrates, lymphocytic									1/28	3/20
Leukemic infiltrates, monocytic									0/28	1/20
Myelofibrosis, focal		2							8/28	1/20

Code: 1 = minimal 3 = moderate P = present N = within normal limits H = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7183	80-7185	80-7189	80-7192	80-7193	80-7199	80-7200	80-7202	80-7204	80-7205	80-7206	80-7214	80-7216	80-7217	80-7224	80-7229	80-7231	80-7233	80-7236	80-7240
BONE MARROW (continued)																				
Hypocellular																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
MESENTERY/ABDOMINAL CAVITY										L						L	L	L		
Lipogranuloma/fat necrosis										P						P	P	P		
CLITORAL GLAND	L			L																
Carcinoma																				
Adenoma	P			P																
LYMPH NODE(S), NOS				L					L			L						L		
Monocytic leukemia																				
Malignant lymphoma																				
Carcinoma, metastatic, clitoral				P								P								
Lymphoid hyperplasia									2									2		
SALIVARY GLAND												N								
HARDERIAN GLAND																				
Leukemic infiltrates, lymphocytic																				
THYMUS																				
Malignant lymphoma																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
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F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7243	80-7244	80-7245	80-7246	80-7251	80-7252	80-7254	80-7256	80-7184*	80-7194*	80-7210*	80-7223*	80-7227*	80-7228*	80-7235*	80-7253*	80-7188**	80-7198**	80-7208**	80-7209**
BONE MARROW (continued)																				
Hypocellular																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
MESENTERY/ABDOMINAL CAVITY																			L	
Lipogranuloma/fat necrosis																			P	
CLITORAL GLAND	L			L																
Carcinoma	P																			
Adenoma				P																
LYMPH NODE(S), NOS	L						L		L	L	L				L					
Monocytic leukemia									P											
Malignant lymphoma										P	P				P					
Carcinoma, metastatic, clitoral	P																			
Lymphoid hyperplasia							2													
SALIVARY GLAND									N											
HARDERIAN GLAND										L										
Leukemic infiltrates, lymphocytic										P										
THYMUS										L										
Malignant lymphoma										P										

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL REPORT
F344 Female Rats
RDX 40.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ORGAN Lesion / Accession Number	80-7211**	80-7212**	80-7215**	80-7219**	80-7234**	80-7239**	80-7242**	80-7257**	TS Incidence	SOMS Incidence
BONE MARROW (continued)										
Hypocellular								4	0/28	1/20
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP										
MESENTERY/ABDOMINAL CAVITY	L					L				
Lipogranuloma/fat necrosis	P					P			4/4	3/3
CLITORAL GLAND										
Carcinoma									1/4	-
Adenoma									3/4	-
LYMPH NODE(S), NOS										
Monocytic leukemia									0/6	1/4
Malignant lymphoma									2/6	3/4
Carcinoma, metastatic, clitoral									1/6	0/4
Lymphoid hyperplasia									3/6	0/4
SALIVARY GLAND										
HARDERIAN GLAND										
Leukemic infiltrates, lymphocytic									-	1/1
THYMUS										
Malignant lymphoma									-	1/1

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SOMS = spontaneous death/moribund sacrifice

PATHOLOGY APPENDIX G

STATISTICAL EVALUATION OF HISTOPATHOLOGIC LESIONS

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	--	0	--	0	--	0	--	6*	2
	Absent	10	--	10	--	10	--	10	--	4	3
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27
Spleen, sinusoidal congestion											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	10*	0
	Absent	10	--	10	--	10	3	10	--	0	18
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	17	36	19	25	27	29	26	4	27

Time = time of sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Spleen, increased pigment											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	3	0	1	7*	4	11*	4	0	18*
	Absent	38	14	36	18	18	23	18	22	4	9
Testicular germinal cell degeneration, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	3	0
	Absent	10	--	10	--	10	--	10	--	7	5
12 mos	Present	0	--	0	--	0	1	0	--	4*	4
	Absent	10	--	10	--	10	2	10	--	6	15
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Prostate, spermatic granuloma											
6 mos	Present	0	--	2	--	2	--	1	--	6*	2
	Absent	10	--	8	--	8	--	9	--	4	3
12 mos	Present	0	--	0	--	1	0	1	--	0	0
	Absent	10	--	10	--	9	3	9	--	10	19
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	38	16	36	19	25	27	29	26	4	27
Prostate, suppurative inflammation											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	0
	Absent	10	--	10	--	10	3	10	--	10	19
24 mos	Present	0	2	1	3	** 2	7**	4*	8	0	19*
	Absent	38	14	35	16	23	20	25	18	4	8

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, medullary papilla necrosis, unilateral/bilateral											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	15*
	Absent	10	--	10	--	10	3	10	--	10	4
24 mos	Present	0	0	0	1	0	0	0	0	0	18*
	Absent	38	17	36	18	25	27	29	26	4	9
Kidney, pyelitis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	1	0	0	0	1	** 0	** 5
	Absent	38	17	36	18	25	27	29	25	4	22

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

** = significant ($p < 0.05$) at this interval only when both SS and SDMS were combined

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Kidney, plyelonephritis											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	1
	Absent	10	--	10	--	10	3	10	--	10	18
24 mos	Present	0	0	0	0	0	2	1	1	0	1
	Absent	38	17	36	19	25	25	28	25	4	26
Urinary bladder, luminal distention											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	18*
	Absent	10	--	10	--	10	3	10	--	10	1
24 mos	Present	0	0	0	2	0	1	0	3	1*	24*
	Absent	38	16	36	17	25	26	29	19	3	4

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY
OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE MALE
FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day) 0.0 SS	0.0 SDMS	0.3 SS	0.3 SDMS	1.5 SS	1.5 SDMS	8.0 SS	8.0 SDMS	40.0 SS	40.0 SDMS
Urinary bladder, cystitis, hemorrhagic/suppurative/ hemorrhagic - suppurative											
6 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	5
12 mos	Present	0	--	0	--	0	0	0	--	0	17*
	Absent	10	--	10	--	10	3	10	--	10	2
24 mos	Present	0	0	0	2	0	1	1	0	0	18*
	Absent	38	16	36	17	25	26	28	22	4	9
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

Time	Lesion	Dose (mg/kg/day)									
		0.0		0.3		1.5		8.0		40.0	
		SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS
Lenticular cataracts											
6 mos	Present	0	--	0	--	0	--	0	--	0	--
	Absent	10	--	10	--	10	--	10	--	10	--
12 mos	Present	0	--	0	--	0	--	0	--	0	0
	Absent	10	--	10	--	10	--	10	--	10	7
24 mos	Present	14	1	4	1	17	3	9	3	23*	9*
	Absent	29	9	41	9	25	9	32	8	5	11
Spleen, extramedullary hematopoiesis											
6 mos	Present	0	0	0	--	0	--	0	--	5*	--
	Absent	10	1	10	--	10	--	10	--	5	--
12 mos	Present	0	0	0	--	0	0	0	--	0	0
	Absent	10	1	10	--	10	1	10	--	10	7
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

TABLE

TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE IN THE FEMALE FISCHER 344 RAT

Statistical Evaluation of Histopathologic Lesions

		Dose (mg/kg/day)									
		0.0		0.3		1.5		8.0		40.0	
Time	Lesion	SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS	SS	SDMS
Spleen, sinusoidal congestion											
6 mos	Present	0	0	0	--	0	--	0	--	0	--
	Absent	10	1	10	--	10	--	10	--	10	--
12 mos	Present	0	0	0	--	0	0	0	--	9*	1
	Absent	10	1	10	--	10	1	10	--	1	6
24 mos	Present	0	0	0	0	0	0	0	0	0	0
	Absent	43	10	45	10	42	12	41	11	28	20
6 mos	Present										
	Absent										
12 mos	Present										
	Absent										
24 mos	Present										
	Absent										

Time = time of scheduled sacrifice

SS = scheduled sacrifice

SDMS = spontaneous death or moribund sacrifice during interval following last scheduled sacrifice

* = significantly different from control group, $p < 0.05$

ADDENDUM HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

NOVEMBER 7, 1983

IITRI PROJECT NUMBER L06121
STUDY NUMBER 6

Donovan E. Gordon, D.V.M., Ph.D.
Consultant Histopathologist
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PATHOLOGY APPENDIX A

IITRI Project Number L06121, Study Number 6
Sponsor Project Number DAMD 17-79-C-9161

ADDENDUM REPORT OF HISTOPATHOLOGIC FINDINGS

Methods

At the request of IIT Research Institute, Hematoxylin-Eosin stained sections of selected additional tissues from all experimental intervals of a twenty-four month chronic toxicity/carcinogenicity study of hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) were examined by light microscopy. This examination was conducted to determine the changes, if any, caused in specific tissues by RDX at 0.3 mg/kg/day, 1.5 mg/kg/day, and 8.0 mg/kg/day dose levels and to determine, if possible, a no-effect level for RDX in each sex of this species. The specific tissues examined were the eye from female rats and the urogenital tissues (urinary bladder and/or prostate, seminal vesicles, and epididymis) from male rats of these dose levels. Previous examination of these tissues from rats which had received 40.0 mg/kg/day RDX and from gross lesions observed at these dose levels had revealed the presence of treatment related lesions. For most animals these tissues had not been previously examined at these dose levels

A total of 218 eye slides from 217 female rats were received on October 12, 1983. The table below indicates the distribution of these females by study interval, dose level, and fate.

RDX LEVEL:	0.3 mg/kg/day		1.5 mg/kg/day		8.0 mg/kg/day	
FATE:	SS*	SDMS**	SS	SDMS	SS	SDMS
6 month IS+ and 0-6 month SDMS	10	-	10	-	10	-
12 month IS and 7-12 month SDMS	10	-	10	-	10	-
24 month TS++ and 13-24 month SDMS	42	9	39	13	40	14

* = scheduled sacrifice ** = spontaneous death/moribund sacrifice
\+ = interim sacrifice ++ = terminal sacrifice

On October 26, 1983 a total of 212 urogenital slides from 212 male test rats were received. The table below indicates the distribution of these males by study interval, dose level, and fate.

RDX LEVEL:	0.3 mg/kg/day		1.5 mg/kg/day		8.0 mg/kg/day	
FATE:	SS*	SDMS**	SS	SDMS	SS	SDMS
6 month IS+ and 0-6 month SDMS	10	-	10	-	10	-
12 month IS and 7-12 month SDMS	10	-	10	-	10	-
24 month TS++ and 13-24 month SDMS	36	17	25	27	28	19

* = scheduled sacrifice ** = spontaneous death/moribund sacrifice
\+ = interim sacrifice ++ = terminal sacrifice

The "Pathology Report" forms and the appendices which accompany this report constitute an accountability of all tissues examined for this addendum report as well as observations previously reported for these tissues. The grading system and abbreviations used on the "Pathology Report" forms and in the tables are as follows:

Grade 1 = minimal severity
Grade 2 = mild severity
Grade 3 = moderate severity
Grade 4 = marked severity
P = present, no grade

N = within normal limits
L = lesion present
M = tissue not present
I = tissue section inadequate
\- = not applicable

Each appendix presents the findings for one study interval as indicated below:

Pathology Appendix A: Six month IS and 0-6 month SDMS
Pathology Appendix B: Twelve month IS and 7-12 month SDMS
Pathology Appendix C: Twenty-four month TS and 13-24 month SDMS

Within each appendix the following tables may by found (in order of presentation):

Incidence of Lesions Considered to be Treatment Related - Males
Lesion Incidence Comparison Table - Males
Histopathology Lesion Severity Incidence Table - Males
Incidence of Lesions Considered to be Treatment Related - Females
Lesion Incidence Comparison Table - Females
Histopathology Lesion Severity Incidence Table - Females

Results:

The examination of ocular and urinary tract tissues from female and male rats respectively of the RDX 0.3 mg/kg/day, RDX 1.5 mg/kg/day, and RDX 8.0 mg/kg/day groups from the 6, 12, and 24 month sacrifice intervals did not reveal any additional treatment related findings. The changes observed in the tissues examined for the first time in preparation of this addendum report were ascribed to naturally occurring disease and in most instances were similar in incidence and/or grade to those observed among concurrent control animals. Therefore, the conclusions presented in the final report dated September 15, 1983 are modified to read:

> "The no-effect level of RDX in female Fischer 344 rats under the conditions of the present study was 8.0 mg/kg/day while the no-effect level of RDX in male Fischer 344 rats could not be not determined."

Other observations:

At the time of the 6 and 12 month histopathologic reports, spermatic granulomas observed in the coagulating gland of the test males were recorded under prostate. These tissues are in close proximity to each other and this lesion frequently obscures the exact identity of the tissue of origin. For the final report, this lesion was reported under the tissue heading of coagulating gland. For purposes of data evaluation in the addendum report, spermatic granuloma observed among males of the 6 to 12 month study interval were recorded under the tissue heading entitled prostate/coagulating gland.

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L06121 SN6
SIX MONTH INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
PROSTATE/COAGULATING GLAND	(10)	-	(10)	-	(10)	-	(10)	-	(10)	(5)
Spermatic granuloma	0/10	-	2/10	-	2/10	-	1/10	-	6/10	2/5

Code: IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
SIX MONTH INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
URINARY BLADDER	(10)	-	(10)	-	(10)	-	(10)	-	(10)	(5)
Muscularis, hemorrhage	0/10	-	0/10	-	0/10	-	0/10	-	0/10	1/5
Muscularis, inflammation, subacute	0/10	-	0/10	-	0/10	-	0/10	-	0/10	1/5
PROSTATE/COAGULATING GLAND	(10)	-	(10)	-	(10)	-	(10)	-	(10)	(5)
Spermatic granuloma	0/10	-	2/10	-	2/10	-	1/10	-	6/10	2/5
Inflammation, interstitial, subacute	0/10	-	0/10	-	0/10	-	0/10	-	0/10	1/5
EPIDIDYMIS	(10)	-	(10)	-	(10)	-	(10)	-	(10)	(5)
Absence of sperm in ducts	0/10	-	0/10	-	0/10	-	0/10	-	1/10	0/5
SEMINAL VESICLE	-	-	(10)	-	(10)	-	(10)	-	-	-

ode: IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
SIX MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6665	80-6668	80-6669	80-6671	80-6683	80-6684	80-6695	80-6704	80-6725	80-6731	IS INCIDENCE	SDMS Incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N		
PROSTATE	N	N	N	N	N	N	N	N	N	N		
EPIDIDYMIS	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN		
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N		
COAGULATING GLAND		L		L								
Spermatic granuloma(s), focal		2		1							2/2	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS - interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
SIX MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6808	80-6812	80-6814	80-6837	80-6842	80-6843	80-6856	80-6858	80-6873	80-6875	IS INCIDENCE	SDMS Incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N		
PROSTATE	N	N	N	N	N	N	N	N	N	N		
EPIDIDYMIS	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN		
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N		
COAGULATING GLAND		L							L			
Spermatic granuloma(s), focal		1							1		2/2	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS - interim sacrifice SDMS = spontaneous death/moribund sacrifice

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L06121 SN6
SIX MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6969	80-6980	80-6983	80-6991	80-6994	80-6999	80-7007	80-7015	80-7016	80-7027	IS INCIDENCE	SDMS Incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N		
PROSTATE	N	N	N	N	N	N	N	N	N	N		
EPIDIDYMIS	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN		
SEMINAL VESICLE	N	N	N	N	N	N	N	N	N	N		
COAGULATING GLAND			L									
Spermatic granuloma(s), focal			2								1/1	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
SIX MONTH INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
NO LESIONS WERE CONSIDERED TREATMENT RELATED IN FEMALES AT THIS INTERIM										

IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
SIX MONTH INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
EYE	(10)	(1)	(10)	-	(10)	-	(10)	-	(10)	-

Code: IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
SIX MONTH INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6733	80-6745	80-6750	80-6764	80-6765	80-6768	80-6782	80-6786	80-6798	80-6806											IS INCIDENCE	SDMS Incidence
EYE	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS - interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
SIX MONTH INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6892	80-6898	80-6915	80-6916	80-6919	80-6921	80-6925	80-6948	80-6950	80-6954											IS INCIDENCE	SDMS Incidence
EYE	NN	NN	NN	NI	NI	NN	NN	NN	NN	NI												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
SIX MONTH INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7045	80-7046	80-7048	80-7050	80-7064	80-7072	80-7086	80-7088	80-7100	80-7106											IS INCIDENCE	SDMS Incidence
EYE	NN	NN	NI	NN	NI	NN	NN	NN	NN	NN												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

PATHOLOGY APPENDIX B

ADDENDUM TO TWELVE MONTH HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

NOVEMBER 7, 1983

IITRI PROJECT NUMBER L06121
STUDY NUMBER 6

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L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
URINARY BLADDER	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
Cystitis, hemorrhagic	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	17/19
Mineralization, uremic	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	4/19
Distention, luminal	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	18/19

Code: IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

GAN esion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
INARY BLADDER	(10)	-	(10)	-	(10)	(3)	(10)	-	(10)	(19)
ystitis, hemorrhagic	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	17/19
istention, luminal	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	18/19
ineralization, uremic	0/10	-	0/10	-	0/10	0/3	0/10	-	0/10	4/19
erosa, microgranuloma	1/10	-	0/10	-	0/10	0/3	0/10	-	0/10	0/19

IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6661	80-6675	80-6677	80-6678	80-6689	80-6690	80-6699	80-6709	80-6723	80-6726											IS INCIDENCE	SDMS Incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6810	80-6817	80-6823	80-6824	80-6829	80-6848	80-6863	80-6870	80-6876	80-6877	80-6822*	80-6836**	80-6872**								IS INCIDENCE	SDMS Incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N									

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6959	80-6964	80-6971	80-6975	80-6976	80-6988	80-7003	80-7004	80-7008	80-7022											IS INCIDENCE	SCMS incidence
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SCMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
NO LESIONS WERE CONSIDERED TREATMENT RELATED IN FEMALES AT THIS INTERIM										

IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	IS INCIDENCE RDX 0.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 0.3 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 1.5 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 8.0 mg/kg/day	SDMS Incidence	IS INCIDENCE RDX 40.0 mg/kg/day	SDMS Incidence
EYE	(10)	(1)	(10)	-	(10)	-	(10)	-	(10)	(7)
Lens, cataract	0/10	0/1	0/10	-	0/10	-	1/10	-	0/10	0/7
TISSUES NOT SPECIFICALLY REQUIRED BY PROTOCOL FOR ANY GROUP										
HARDERIAN GLAND	-	-	-	-	-	-	(1)	-	(1)	-
Dacryoadenitis	-	-	-	-	-	-	1/1	-	1/1	-

Code: IS = interim sacrifice
- = not applicable
SDMS = spontaneous death/moribund sacrifice
( ) = number of animals for which tissue was represented

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6735	80-6737	80-6755	80-6763	80-6774	80-6781	80-6783	80-6785	80-6789	80-6807											IS INCIDENCE	SDMS Incidence
EYE	NN	NI	NN	NN	NN	NN	NN	NN	NI	NN												

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6885	80-6897	80-6899	80-6907	80-6918	80-6934	80-6935	80-6939	80-6941	80-6944	80-6894**									IS INCIDENCE	SDMS Incidence
EYE	NI	NN	NN	NN	NN	NN	NI	NN	NN	NN	NN										

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
TWELVE MONTH INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7034	80-7047	80-7051	80-7067	80-7068	80-7080	80-7087	80-7095	80-7101	80-7102	IS INCIDENCE	SDMS Incidence
EYE	NN	NN	NN	NN	NN	NN	NN	NL	NN	NN		
Lens, cataract								P			1/10	-
TISSUES NOT SPECIFICALLY REQUIRED												
BY PROTOCOL FOR ANY GROUP												
HARDERIAN GLAND						L						
Dacryoadenitis, unilateral						1					1/10	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
IS = interim sacrifice SDMS = spontaneous death/moribund sacrifice

PATHOLOGY APPENDIX C

ADDENDUM TO FINAL HISTOPATHOLOGY REPORT OF A TWENTY-FOUR MONTH CHRONIC TOXICITY/CARCINOGENICITY STUDY OF HEXAHYDRO-1,3,5-TRINITRO-1,3,5-TRIAZINE (RDX) IN THE FISCHER 344 RAT

NOVEMBER 7, 1983

IITRI PROJECT NUMBER L06121
STUDY NUMBER 6

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L06121 SN6
FINAL INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence RDX 0.0 mg/kg/day	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence RDX 0.3 mg/kg/day	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence RDX 1.5 mg/kg/day	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence RDX 8.0 mg/kg/day	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence RDX 40.0 mg/kg/day
URINARY BLADDER	(38)	(16)	(36)	(19)	(25)	(17)	(29)	(22)	(4)	(27)
Cystitis, suppurative	0/38	0/16	0/36	0/19	0/25	0/27	1/29	0/22	0/4	0/27
Cystitis, hemorrhagic-suppurative	0/38	0/16	0/36	2/19	0/25	1/27	0/29	0/22	0/4	17/27
Cystitis, hemorrhagic	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/22	0/4	1/27
Mineralization, uremic	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/22	0/4	1/27
Distention, luminal	0/38	0/16	0/36	2/19	0/25	1/27	0/29	3/22	1/4	23/27
PROSTATE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Inflammation, suppurative	0/38	2/16	1/36	3/19	2/25	7/27	4/29	8/26	0/4	19/27

Code: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
– = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	RDX 0.0 mg/kg/day TS Incidence	RDX 0.0 mg/kg/day SDMS Incidence	RDX 0.3 mg/kg/day TS Incidence	RDX 0.3 mg/kg/day SDMS Incidence	RDX 1.5 mg/kg/day TS Incidence	RDX 1.5 mg/kg/day SDMS Incidence	RDX 8.0 mg/kg/day TS Incidence	RDX 8.0 mg/kg/day SDMS Incidence	RDX 40.0 mg/kg/day TS Incidence	RDX 40.0 mg/kg/day SDMS Incidence
URINARY BLADDER	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(22)	(4)	(27)
Transitional cell carcinoma	1/38	0/16	0/36	0/19	0/25	0/27	0/29	0/22	0/4	0/27
Leukemic infiltrates, lymphocytic	0/38	1/16	0/36	4/19	0/25	1/27	0/29	0/22	0/4	1/27
Leukemic infiltrates, monocytic	3/38	0/16	1/36	0/19	0/25	0/27	0/29	0/22	0/4	2/27
Cystitis, suppurative	0/38	0/16	0/36	0/19	0/25	0/27	1/29	0/22	0/4	0/27
Cystitis, hemorrhagic-suppurative	0/38	0/16	0/36	2/19	0/25	1/27	0/29	0/22	0/4	17/27
Cystitis, hemorrhagic	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/22	0/4	1/27
Lymphoid aggregates, submucosal	1/38	0/16	0/36	0/19	1/25	0/27	3/29	0/22	0/4	0/27
Mineralization, uremic	0/38	0/16	0/36	0/19	0/25	0/27	0/29	0/22	0/4	1/27
Distention, luminal	0/38	0/16	0/36	2/19	0/25	1/27	0/29	3/22	1/4	23/27
Mucosal hyperplasia	0/38	0/16	0/36	0/19	0/25	0/27	1/29	0/22	0/4	0/27
PROSTATE	(38)	(16)	(36)	(19)	(25)	(27)	(29)	(26)	(4)	(27)
Adenoma	1/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Leukemic infiltrates, lymphocytic	0/38	0/16	0/36	1/19	0/25	1/27	0/29	1/26	0/4	0/27
Leukemic infiltrates, monocytic	0/38	1/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Hyperplasia, adenomatous	0/38	1/16	1/36	0/19	0/25	2/27	0/29	0/26	1/4	0/27
Inflammation, subacute	1/38	0/16	0/36	0/19	0/25	0/27	0/29	0/26	0/4	0/27
Inflammation, chronic-active	15/38	5/16	13/36	6/19	6/25	7/27	6/29	5/26	1/4	1/27
Inflammation, suppurative	0/38	2/16	1/36	3/19	2/25	7/27	4/29	8/26	0/4	19/27

: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL INTERIM

MALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

RGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
ROSTATE (continued)										
Microabscesses	0/38	0/16	0/36	1/19	0/25	1/27	0/29	0/26	0/4	1/27
Cysts	0/38	0/16	0/36	0/19	0/25	0/27	0/29	1/26	0/4	0/27

de: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
– = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN / Lesion — Accession Number	80-6659	80-6660	80-6662	80-6664	80-6667	80-6670	80-6673	80-6674	80-6679	80-6681	80-6682	80-6685	80-6686	80-6688	80-6691	80-6693	80-6694	80-6696	80-6697	80-6698
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic																				
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																				
PROSTATE	N	N	L	L	N	N	N	N	N	L	L	L	L	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Hyperplasia, adenomatous, focal													2							
Inflammation, chronic-active			2	1						1	2	1	1							
Microabscesses																				
Inflammation, suppurative																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6701	80-6702	80-6705	80-6707	80-6708	80-6710	80-6711	80-6713	80-6714	80-6715	80-6716	80-6719	80-6722	80-6727	80-6728	80-6730	80-6666*	80-6672*	80-6680*	80-6692*
URINARY BLADDER	N	N	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	L	N
Leukemic infiltrates, lymphocytic																				
Leukemic infiltrates, monocytic								P												
Cystitis, hemorrhagic-suppurative																				
Distention, luminal																			P	
PROSTATE	N	L	L	L	N	N	N	N	N	L	N	L	L	L	N	L	N	L	L	L
Leukemic infiltrates, lymphocytic																				
Hyperplasia, adenomatous, focal																				
Inflammation, chronic-active		1	1	1								2	1	1		2		1	1	
Microabscesses																				
Inflammation, suppurative										3										3

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6700*	80-6703*	80-6717*	80-6721*	80-6729*	80-6732*	80-6658**	80-6663**	80-6676**	80-6687**	80-6706**	80-6712**	80-6718**	80-6720**	80-6724**						TS Incidence	SDMS Incidence
URINARY BLADDER	N	L	N	L	N	N	L	N	N	N	N	N	L	L	L							
Leukemic infiltrates, lymphocytic		P		P									P	P							0/36	4/19
Leukemic infiltrates, monocytic																					1/36	0/19
Cystitis, hemorrhagic-suppurative							4								1						0/36	2/19
Distention, luminal							P														0/36	2/19
PROSTATE	N	L	N	N	N	N	L	L	N	L	L	N	L	N	L							
Leukemic infiltrates, lymphocytic		P																			0/36	1/19
Hyperplasia, adenomatous, focal																					1/36	0/19
Inflammation, chronic-active								1			1		2		1						13/36	6/19
Microabscesses										P											0/36	1/19
Inflammation, suppurative							4			3											1/36	3/19

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN / Lesion — Accession Number	80-6809	80-6811	80-6815	80-6820	80-6827	80-6828	80-6830	80-6832	80-6833	80-6834	80-6838	80-6839	80-6841	80-6847	80-6851	80-6853	80-6854	80-6860	80-6862	80-6865
URINARY BLADDER	N	N	N	N	N	L	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Leukemic infiltrates, lymphocytic																				
Cystitis, hemorrhagic-suppurative																				
Lymphoid aggregates, submucosal, focal						2														
Distention, luminal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6869	80-6871	80-6874	80-6879	80-6882	80-6813*	80-6818*	80-6821*	80-6825*	80-6831*	80-6835*	80-6840*	80-6845*	80-6849*	80-6857*	80-6864*	80-6881*	80-6816**	80-6819**	80-6826**
URINARY BLADDER	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	L	N	N
Leukemic infiltrates, lymphocytic																		P		
Cystitis, hemorrhagic-suppurative																				
Lymphoid aggregates, submucosal, focal																				
Distention, luminal																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6844**	80-6846**	80-6850**	80-6852**	80-6855**	80-6859**	80-6861**	80-6866**	80-6867**	80-6868**	80-6878**	80-6880**	TS Incidence	SDMS Incidence
URINARY BLADDER	N	N	L	N	N	N	N	N	N	N	N	N		
Leukemic infiltrates, lymphocytic													0/25	1/27
Cystitis, hemorrhagic-suppurative			4										0/25	1/27
Lymphoid aggregates, submucosal, focal													1/25	0/27
Distention, luminal			P										0/25	1/27

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6958	80-6960	80-6962	80-6963	80-6967	80-6968	80-6973	80-6978	80-6986	80-6987	80-6989	80-6992	80-6993	80-6995	80-6996	80-6997	80-6998	80-7006	80-7009	80-7011
URINARY BLADDER	N	L	N	N	N	N	N	N	N	L	N	N	N	L	N	N	N	N	N	L
Cystitis, suppurative														2						
Lymphoid aggregates, submucosal, focal		1								1										1
Distention, luminal																				
Mucosal hyperplasia																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

DDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7014	80-7017	80-7018	80-7019	80-7023	80-7029	80-7030	80-7031	80-7032	80-6961*	80-6965*	80-6970*	80-6979*	80-6981*	80-6985*	80-6990*	80-7021*	80-7025*	80-7026*	80-6966**
URINARY BLADDER	N	N	N	L	N	N	N	N	N	N	N	N	M	N	N	L	M	L	L	M
Cystitis, suppurative																				
Lymphoid aggregates, submucosal, focal																				
Distention, luminal																P		P	P	
Mucosal hyperplasia				2																

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
[illegible] = [illegible] = [illegible] death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Male Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

)DENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6972**	80-6974**	80-6977**	80-6982**	80-6984**	80-7000**	80-7001**	80-7002**	80-7005**	80-7010**	80-7012**	80-7013**	80-7020**	80-7024**	80-7028**						TS Incidence	SDMS Incidence
URINARY BLADDER	N	N	M	N	N	N	N	N	N	N	N	N	N	N	N							
Cystitis, suppurative																					1/29	0/22
Lymphoid aggregates, submucosal, focal																					3/29	0/22
Distention, luminal																					0/29	3/22
Mucosal hyperplasia																					1/29	0/22

)de: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

INCIDENCE OF LESIONS CONSIDERED TO BE TREATMENT RELATED

RGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
YE	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(11)	(28)	(20)
Lens, cataract	14/43	1/10	4/45	1/10	17/42	3/12	9/41	3/11	23/28	9/20
Lens-induced inflammation	0/43	1/10	0/45	0/10	4/42	0/12	0/41	0/11	9/28	2/20
Degeneration, retinal	11/43	0/10	4/45	0/10	8/42	2/12	8/41	2/11	10/28	2/20

de: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL INTERIM

FEMALE F344 RATS

ADDENDUM REPORT: table includes previously reported data

LESION INCIDENCE COMPARISON TABLE

ORGAN Lesion	TS Incidence RDX 0.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 0.3 mg/kg/day	SDMS Incidence	TS Incidence RDX 1.5 mg/kg/day	SDMS Incidence	TS Incidence RDX 8.0 mg/kg/day	SDMS Incidence	TS Incidence RDX 40.0 mg/kg/day	SDMS Incidence
EYE	(43)	(10)	(45)	(10)	(42)	(12)	(41)	(11)	(28)	(20)
Leukemic infiltrates, lymphocytic	0/43	0/10	0/45	1/10	0/42	0/12	0/41	0/11	1/28	0/20
Keratitis, chronic	2/43	0/10	1/45	0/10	0/42	0/12	1/41	0/11	6/28	2/20
Lens, cataract	14/43	1/10	4/45	1/10	17/42	3/12	9/41	3/11	23/28	9/20
Lens-induced inflammation	0/43	1/10	0/45	0/10	4/42	0/12	0/41	0/11	9/28	2/20
Degeneration, retinal	11/43	0/10	4/45	0/10	8/42	2/12	8/41	2/11	10/28	2/20
Phthisis bulbi	1/43	0/10	1/45	0/10	0/42	0/12	1/41	1/11	1/28	0/20
Cyst, choroid	0/43	0/10	1/45	0/10	0/42	0/12	0/41	0/11	0/28	0/20
TISSUES NOT SPECIFICALLY REQUIRED										
BY PROTOCOL FOR ANY GROUP										
HARDERIAN GLAND	-	-	(3)	-	(2)	-	(2)	-	-	(1)
Leukemic infiltrates, lymphocytic	-	-	0/3	-	0/2	-	0/2	-	-	1/1
Leukemic infiltrates, monocytic	-	-	0/3	-	0/2	-	1/2	-	-	0/1
Dacryoadenitis	-	-	3/3	-	2/2	-	1/2	-	-	0/1

: TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice
- = not applicable ( ) = number of animals for which tissue was represented

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6734	80-6736	80-6739	80-6740	80-6741	80-6742	80-6743	80-6746	80-6747	80-6748	80-6751	80-6753	80-6754	80-6756	80-6757	80-6758	80-6759	80-6760	80-6762	80-6766
EYE	NN	NN	NN	NL	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NN	NI	NN	NN	NL
Leukemic infiltrates, lymphocytic																				
Keratitis, chronic, focal/multifocal,																				
unilateral																				
Lens, cataract, unilateral/bilateral				P																P
Degeneration, retinal, unilateral/																				
bilateral				2																
Phthisis bulbi, unilateral																				
Cyst, choroid																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND																	L			L
Dacryoadenitis, unilateral/bilateral																	1			2

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6767	80-6769	80-6770	80-6772	80-6773	80-6775	80-6778	80-6779	80-6780	80-6784	80-6787	80-6788	80-6790	80-6791	80-6792	80-6793	80-6794	80-6795	80-6796	80-6797
EYE	LM	LM	NN	NN	NI	NN	NN	NN	NN	LL	NN	NL	LL	NN	NN	NN	NN	NN	NN	NN
Leukemic infiltrates, lymphocytic																				
Keratitis, chronic, focal/multifocal,																				
unilateral		3																		
Lens, cataract, unilateral/bilateral		P											P							
Degeneration, retinal, unilateral/																				
bilateral										2		2	3							
Phthisis bulbi, unilateral	P																			
Cyst, choroid		P																		
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND							L													
Dacryoadenitis, unilateral/bilateral							3													

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice · SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 0.3 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6799	80-6801	80-6803	80-6804	80-6805	80-6752*	80-6771*	80-6776*	80-6800*	80-6738**	80-6744**	80-6749**	80-6761**	80-6777**	80-6802**						TS Incidence	SDMS Incidence
EYE	NN	NN	NN	NN	NN	NL	LL	NN	NN	NN	NN	NN	NN	NN	NN							
Leukemic infiltrates, lymphocytic							P														0/45	1/10
Keratitis, chronic, focal/multifocal,																						
unilateral																					1/45	0/10
Lens, cataract, unilateral/bilateral						P															4/45	1/10
Degeneration, retinal, unilateral/																						
bilateral																					4/45	0/10
Phthisis bulbi, unilateral																					1/45	0/10
Cyst, choroid																					1/45	0/10
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP																						
HARDERIAN GLAND																						
Dacryoadenitis, unilateral/bilateral																					3/3	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6883	80-6884	80-6887	80-6888	80-6889	80-6891	80-6895	80-6896	80-6901	80-6902	80-6904	80-6905	80-6906	80-6908	80-6909	80-6910	80-6913	80-6914	80-6920	80-6922
EYE	NN	NN	NN	NN	NL	NL	NL	LL	LL	LL	NN	NN	NN	NM	NL	NN	NN	LL	NN	NN
Lens, cataract, unilateral/bilateral					P	P	P	P	P	P					P			P		
Degeneration, retinal, unilateral/																				
bilateral									2	3								3		
Lens-induced inflammation, unilateral/																				
bilateral								P												
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND																				
Dacryoadenitis, unilateral/bilateral																				

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Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6923	80-6924	80-6926	80-6927	80-6929	80-6931	80-6932	80-6933	80-6937	80-6938	80-6940	80-6942	80-6943	80-6945	80-6946	80-6947	80-6949	80-6951	80-6952	80-6953
EYE	NN	NN	LL	LL	NL	NL	NN	NN	NL	LM	LM	NL	NN	NN	NN	NN	NN	NN	NN	NN
Lens, cataract, unilateral/bilateral			P	P	P	P			P	P	P	P								
Degeneration, retinal, unilateral/																				
bilateral			2	2	3				2		3									
Lens-induced inflammation, unilateral/																				
bilateral					P					2		P								
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND						L				L										
Dacryoadenitis, unilateral/bilateral						1				2										

continued next page

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 1.5 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-6956	80-6957	80-6890*	80-6903*	80-6917*	80-6955*	80-6886**	80-6893**	80-6900**	80-6911**	80-6912**	80-6928**	80-6930**	80-6936**							TS Incidence	SDMS Incidence
EYE	LI	NN	NN	LL	NN	NN	LL	NN	NL	NN	NN	NN	NN	NN								
Lens, cataract, unilateral/bilateral	P			P			P		P												17/42	3/12
Degeneration, retinal, unilateral/																						
bilateral				2			3														8/42	2/12
Lens-induced inflammation, unilateral/																						
bilateral																					4/42	0/12
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP																						
HARDERIAN GLAND																						
Dacryoadenitis, unilateral/bilateral																					2/2	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
2 = mild 4 = severe L = lesion present I = tissue section inadequate ** = moribund sacrifice
TS = terminal sacrifice SDMS = spontaneous death/moribund sacrifice

L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7033	80-7035	80-7037	80-7038	80-7039	80-7040	80-7041	80-7042	80-7043	80-7044	80-7049	80-7052	80-7054	80-7055	80-7056	80-7057	80-7058	80-7060	80-7061	80-7062
EYE	NN	NN	NN	NN	NN	NN	NN	NL	NN	NN	NN	NN	NL	NL	NI	NN	NN	LL	NL	NN
Keratitis, chronic, focal/multifocal,																				
unilateral								1												
Lens, cataract, unilateral/bilateral													P	P				P	P	
Degeneration, retinal, unilateral/																				
bilateral													3	2				2	2	
Phthisis bulbi, unilateral																				
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND																				
Leukemic infiltrates, monocytic																				
Dacryoadenitis, unilateral/bilateral																				

continued next page

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06121 SN6
INAL INTERIM
344 Female Rats
DX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

DENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7063	80-7065	80-7066	80-7069	80-7070	80-7073	80-7075	80-7078	80-7079	80-7081	80-7083	80-7090	80-7091	80-7092	80-7093	80-7094	80-7096	80-7097	80-7098	80-7104
EYE	NN	NN	NN	NN	NN	NM	NN	LL	LL	NN	NN	LL	NN	NN	NN	NN	NN	NM	LL	NN
Keratitis, chronic, focal/multifocal, unilateral																				
Lens, cataract, unilateral/bilateral								P	P			P							P	
Degeneration, retinal, unilateral/ bilateral									2			3							3	
Phthisis bulbi, unilateral																			P	
TISSUES NOT SPECIFICALLY REQUIRED																				
BY PROTOCOL FOR ANY GROUP																				
HARDERIAN GLAND	L																		L	
Leukemic infiltrates, monocytic																			P	
Dacryoadenitis, unilateral/bilateral	2																			

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de: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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L06121 SN6
FINAL INTERIM
F344 Female Rats
RDX 8.0 mg/kg/day

HISTOPATHOLOGY LESION SEVERITY INCIDENCE TABLE

ADDENDUM REPORT: table includes previously reported data

ORGAN Lesion / Accession Number	80-7107	80-7074*	80-7076*	80-7082*	80-7085*	80-7089*	80-7103*	80-7105*	80-7036**	80-7053**	80-7059**	80-7071**	80-7077**	80-7084**	80-7099**						TS Incidence	SDMS Incidence
EYE	LL	LL	MI	II	NN	NN	II	NN	NN	NN	NN	NN	LM	NN	LI							
Keratitis, chronic, focal/multifocal,																						
unilateral																					1/41	0/11
Lens, cataract, unilateral/bilateral	P	P											P		P						9/41	3/11
Degeneration, retinal, unilateral/																						
bilateral	2	3											3								8/41	2/11
Phthisis bulbi, unilateral		P																			1/41	1/11
TISSUES NOT SPECIFICALLY REQUIRED																						
BY PROTOCOL FOR ANY GROUP																						
HARDERIAN GLAND																						
Leukemic infiltrates, monocytic																					1/2	-
Dacryoadenitis, unilateral/bilateral																					1/2	-

Code: 1 = minimal 3 = moderate P = present N = within normal limits M = tissue not present * = spontaneous death
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