

Brain (000130) + Spinal cord (000520):
- Glioma (000190) + Ependymoma (000160)

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)
Brain + Spinal Cord	(BSC) IN 79-91	1	0 1 0 0	0.608 0.594 0.660
Glioma+Ependymoma	(GE) IN 79-91	2	26 14 13 12	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	-	-	0 1 0 0	

Uterus (000650):
- sarcoma (000400) + myoma (000280) +Leimyosarcoma (000404)

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)	
Uterus	(UT) IN 79-91	1	0 0 0 1	0.107 0.087 0.094	
Sarcoma+Myoma+Lei.	(SML) IN 79-91	2	25 15 12 11		
			IN 100-100	1		1 0 1 1
			IN 100-100	2		24 12 8 12
			FA 50	1		1 0 0 0
			FA 50	2		92 46 49 47
			FA 56	1		0 0 0 1
			FA 56	2		90 46 48 46
			FA 87	1		0 0 1 0
			FA 87	2		50 23 24 21
			FA 91	1		1 0 0 0
			FA 91	2		42 21 19 18
			FA 92	1		0 0 0 1
			FA 92	2		40 20 18 17
			FA 93	1		0 1 0 0
			FA 93	2		37 18 18 16
			FA 95	1		0 1 0 0
			FA 95	2		34 16 18 16
			FA 97	1		0 0 1 0
			FA 97	2		33 14 16 14
			FA 99	1	0 1 0 0	
FA 99	2	26 13 10 13				
Spontaneous tumor pct: 3% in ctrl. - Total	-	-	-	3 3 3 4		

Lung (000290):
- adenoma (000100) + carcinoma (000140) + adenocarcinoma (000141)

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)	
Lungs	(LUN) IN 53-78	1	3 0 1 0	0.931 0.919 0.923	
Adenoma+Carc+Adenocarc	(ACA) IN 53-78	2	21 10 17 17		
			IN 79-91	1		1 3 2 1
			IN 79-91	2		24 12 11 11
			IN 92-99	1		0 1 1 0
			IN 92-99	2		14 5 7 5
			IN 100-100	1		5 2 2 1
			IN 100-100	2		20 10 7 12
			FA 75	1		1 0 0 0
			FA 75	2		72 38 34 33

FA 78	1	0	1	0	0
FA 78	2	68	36	32	31
FA 90	1	1	0	0	0
FA 90	2	44	22	20	18
FA 92	1	0	1	0	0
FA 92	2	40	19	18	18
FA 95	1	0	1	0	0
FA 95	2	34	16	18	16
FA 98	1	1	0	1	0
FA 98	2	29	14	12	14

Spontaneous tumor pct: 12% in ctrl. - Total - 12 9 7 2

Pancreas (000380):

- **insuloma (000220) + carcinoma (000140)**

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)
Pancreas	(PAN) IN 79-91	1	0 1 1 0	0.398 0.349 0.387
Insuloma+Carcinoma	(IC) IN 79-91	2	26 14 12 12	
		FA 97	1	0 0 1 0	
		FA 97	2	33 14 16 14	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 2 0	

Analysis #6 (Male):

Pituitary (000410) + Thyroid (000610) + Adrenal (000100) + Parathyroids (000390):

- **Adenoma (000100) + Carcinoma (000140)**

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)
Combination	(COMB) IN 53-78	1	0 0 0 1	0.254 0.232 0.244
Adenoma + Carcinoma	(AC) IN 53-78	2	17 6 9 5	
		IN 92-104	1	2 0 0 1	
		IN 92-104	2	24 12 8 12	
		IN 105-105	1	7 4 3 4	
		IN 105-105	2	33 19 12 15	
Spontaneous tumor pct: 9% in ctrl. - Total			-	9 4 3 6	

Analysis #6 (Female):

Pituitary (000410) + Thyroid (000610) + Adrenal (000100) + Parathyroids (000390):

- **Adenoma (000100) + Carcinoma (000140)**

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT.GE.OBSERVED)
Combination	(COMB) IN 53-78	1	1 1 0 0	0.640 0.620 0.633
Adenoma+Carcinoma	(AC) IN 53-78	2	24 10 18 17	
		IN 79-91	1	0 2 1 2	
		IN 79-91	2	26 12 12 10	
		IN 92-99	1	1 3 0 0	
		IN 92-99	2	13 5 9 5	
		IN 100-100	1	8 7 3 4	
		IN 100-100	2	17 5 6 9	

FA 91	1	0	1	0	0
FA 91	2	43	20	19	18
FA 95	1	1	0	0	0
FA 95	2	33	17	18	16

Spontaneous tumor pct: 11% in ctrl. - Total - 11 14 4 6

IIId. Summary of Mouse Study (Study No. 4184/87)

For the male as well as female mice, no statistically significant positive linear trend or increased mortality was detected in the treated groups when compared with the control.

None of the tested tumor types showed any statistically significant positive linear trend or increased incidence in the treated groups when compared with the control for the male mice. But, for the female mice, a significant linear dose tumor-trend was indicated for adenoma (hepatocellular) for the liver.

Additional analyses (as requested by the Reviewing Pharmacologist) for the male as well as female mice showed no statistically significant dose-tumor positive linear trend in the treated groups when compared with the control.

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IV. SUMMARY

Rat Study (Study No. 3805/86)

For the male as well as female rats, no statistically significant positive linear trend or increased mortality was detected in the treated groups when compared with the control.

None of the tested tumor types showed any statistically significant positive linear trend or increased incidence in the treated groups when compared with the control.

From the survival criteria, it can be concluded that enough numbers of rats were exposed to the drug for a sufficient amount of time in both sexes. From the weight gain criteria, it can be concluded that the high dose used (0.8 mg/kg/day) may be close to the maximum tolerated dose for both sexes. However, to draw any final conclusion in this regard, all clinical signs and histopathological effects must be taken into consideration.

Additional analyses (as requested by the Reviewing Pharmacologist) for the male as well as female rats showed no statistically significant dose-tumor positive linear trend in the treated groups when compared with the control.

Mouse Study (Study No. 4184/87)

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None of the tested tumor types showed any statistically significant positive linear trend or increased incidence in the treated groups when compared with the control for the male mice. But, for the female mice, a significant linear dose tumor-trend was indicated for adenoma (hepatocellular) for the liver.

Additional analyses (as requested by the Reviewing Pharmacologist) for the male as well as female mice showed no statistically significant dose-tumor positive linear trend in the treated groups when compared with the control.

/S/

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Concur: Dr. Lin 8/31/99.

Dr. Huque **/S/** 9/1/99

cc: Archival NDA 20-938
HFD-550/Lewin
HFD-550/Yang
HFD-550/Weir
HFD-550/Hyde
HFD-550/Midthun
HFD-550/Division File
HFD-725/Taneja
HFD-725/Lin
HFD-725/Huque
HFD-725/Division File
HFD-725/Chron

There are a total of 86 pages (40 pages of text, 1 page titled Appendix, 40 pages of tables, 4 pages of figures and 1 page containing references) in this review.

APPENDIX

Statistical Interpretation of Significance in Evaluation of Tumor
Data Analyses Currently Adopted by CDER Divisions of Biometrics

- Exact Test - The statistical interpretation of significance is based on the exact test, if one of the two following situation applies.

1. The tumor is found either fatal to all the animals or non-fatal to all the animals.
2. The tumor is fatal only to some but not to all animals, and time-intervals for both situations of lethality do not overlap.

The exact test is done using the Permutation test with general scores, which are the actual dose values. When the scores are set to be equally spaced, the above test is known as the Cochran-Armitage test.

- Asymptotic test - The statistical interpretation of significance is based on the asymptotic test, if none of the above situations applies. The asymptotic test uses the Z-statistic, following the standard normal distribution.

- Cutoff Point for P-Value - To adjust for the effect of multiple testing, one can use a rule proposed by Haseman. A modified rule, proposed by the Divisions of Biometrics, CDER/FDA is applied to the trend tests in the review. In order to keep the overall type-I error at the level of about 10%, this rule states:

1. Tumors with a spontaneous tumor rate of 1% or less may be tested at the 0.025 significance level.
2. Otherwise, the 0.005 significance level may be used.

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Table 1a

Number of Animals
Species: Rat
Sex: Male

	Treatment Group				Total
	CTRL	LOW	MED	HIGH	
	Count	Count	Count	Count	Count
Time Interval					
0-52	3	.	1	.	4
53-78	5	6	2	2	15
79-91	12	6	2	4	24
92-104	12	10	5	9	36
105-106	68	28	40	35	171
Total	100	50	50	50	250

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Table 1b

Number of Animals
Species: Rat
Sex: Female

	Treatment Group				Total
	CTRL	LOW	MED	HIGH	
	Count	Count	Count	Count	Count
Time Interval					
0-52	1		1	2	4
53-78	8	4	5	5	22
79-91	13	6	7	2	28
92-104	14	6	6	6	32
105-106	64	34	31	35	164
Total	100	50	50	50	250

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Table 2a

Analysis of Mortality
 Species: Rat
 Sex: Male

	Dose											
	CTRL			LOW			MED			HIGH		
	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died
Time (-wks)												
0-52	3	100	3.0	.	.	.	1	50	2.0	.	.	.
53-78	5	97	8.0	6	50	12.0	2	49	6.0	2	50	4.0
79-91	12	92	20.0	6	44	24.0	2	47	10.0	4	48	12.0
92-104	12	80	32.0	10	38	44.0	5	45	20.0	9	44	30.0
105-106	68	100	68.0	28	50	56.0	40	50	80.0	35	50	70.0

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Table 2b

Analysis of Mortality
 Species: Rat
 Sex: Female

	Dose											
	CTRL			LOW			MED			HIGH		
	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died
Time (-wks)												
0-52	1	100	1.0	.	.	.	1	50	2.0	2	50	4.0
53-78	8	99	9.0	4	50	8.0	5	49	12.0	5	48	14.0
79-91	13	91	22.0	6	48	20.0	7	44	26.0	2	43	18.0
92-104	14	78	36.0	8	40	32.0	6	37	38.0	6	41	30.0
105-106	64	100	64.0	34	50	68.0	31	50	62.0	35	50	70.0

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Table 3a

Dose-Mortality Trend Tests

This test is run using Trend and Homogeneity Analyses of Proportions and Life Table Data Version 2.1, by Donald G. Thomas, National Cancer Institute

Species: Rat
Sex: Male

Method	Time-Adjusted Trend Test	Statistic	P Value
Cox	Dose-Mortality Trend	0.56	0.4552
	Depart from Trend	6.24	0.0441
	Homogeneity	6.80	0.0786
Kruskal-Wallis	Dose-Mortality Trend	0.66	0.4174
	Depart from Trend	5.97	0.0504
	Homogeneity	6.63	0.0846

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Table 3b

Dose-Mortality Trend Tests

This test is run using Trend and Homogeneity Analyses of Proportions and Life Table Data Version 2.1, by Donald G. Thomas, National Cancer Institute

Species: Rat
Sex: Female

Method	Time-Adjusted Trend Test	Statistic	P Value
Cox	Dose-Mortality Trend	0.17	0.6797
	Depart from Trend	0.71	0.7014
	Homogeneity	0.88	0.8303
Kruskal-Wallis	Dose-Mortality Trend	0.10	0.7477
	Depart from Trend	0.67	0.7146
	Homogeneity	0.78	0.8553

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Table 4 (Part I)
Organs and Organ Codes (Rat)

000100 Adrenals
000130 Brain
000140 Caecum
000160 Epididymides
000200 Heart
000250 Kidneys
000280 Liver
000290 Lungs
000301 Lymph node (mandibular)
000302 Lymph node (mesenteric)
000320 Mammary gland
000330 Mesentery
000370 Ovaries
000380 Pancreas
000390 Parathyroids
000410 Pituitary
000430 Prostate
000450 Retroperitoneum
000480 Salivary gland
000490 Seminal vesicle
000510 Skin
000530 Spleen
000540 Sternum
000550 Stomach
000560 Testicles
000590 Thymus
000610 Thyroids
000650 Uterus
000651 Uterine region
001000 Localisation unknown
001100 Multiple Organs

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Table 4 (Part II)
Tumors and Tumor Codes (Rat)

000100	Adenoma
000102	Adenoma (fibro-)
000103	Adenoma (hepatocellular)
000130	Angioma
000140	Carcinoma
000141	Carcinoma (adeno-)
000143	Carcinoma (squamous cell)
000160	Ependymoma
000171	Fibroma (adeno-)
000172	Fibroma (neuro-)
000190	Glioma
000200	Haemangioma
000210	Histiocytoma
000220	Insuloma
000230	Leukaemia
000240	Lipoma
000241	Lipoma (fibro-)
000250	Luteoma
000260	Lymphangioma
000270	Lymphoma
000280	Myoma
000300	Papilloma
000310	Phaeochromocytoma
000400	Sarcoma
000401	Sarcoma (angio-)
000403	Sarcoma (fibro-)
000405	Sarcoma (neuro-)
000440	Splenoma
000460	Thymoma
001001	Tumour (general., mastopathia prolifer.)
001002	Tumour (granulosa cell-)
001003	Tumour (interstitial cell-)
001004	Tumour (Sertoli-cell-)
001100	Undifferentiated cell malignant growth

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Table 5a

Analysis of Carcinogenic Potential in Male Rat
Test of Dose-Response (Tumor) Positive Linear Trend

Dose Levels Included: CTRL LOW MED HIGH (0 0.4 0.6 0.8)
Missing value in Tumor-Caused Death is treated as tumor not causing death
Tumor-Type: IN: Incidental (nonfatal) tumor, FA: Fatal tumor.

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLE-----	EXACT PROB	ASYMP TOTIC	ASYMP (CONTI NUITY CORR)
Adrenals Adenoma	(000100) (000100)	IN 79-91 IN 79-91	1 2	0 0 1 0 12 6 1 4			
		IN 92-104 IN 92-104	1 2	0 0 1 1 12 10 4 8			
		IN 105-106 IN 105-106	1 2	15 7 5 6 53 21 35 29			
Spontaneous tumor pct: 15% in ctrl. - Total				-	15 7 7 7		0.6684 0.6480 0.7467
Adrenals Carcinoma	(000100) (000140)	IN 105-106 IN 105-106	1 2	0 0 1 0 68 28 39 35	0.3310	0.2774	0.6941
		FA 99 FA 99	1 2	0 1 0 0 75 33 42 36			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 1 0		
Adrenals Pheochromocytoma	(000100) (000310)	IN 105-106 IN 105-106	1 2	1 0 0 0 67 28 40 35	1.0000	0.8732	0.9964
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0		
Brain Angioma	(000130) (000130)	IN 53-78 IN 53-78	1 2	1 0 0 0 4 6 2 2	1.0000	0.8940	0.9988
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0		
Brain Ependymoma	(000130) (000160)	FA 72 FA 72	1 2	1 0 0 0 93 46 48 49	1.0000	0.8716	0.9964
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0		
Brain Glioma	(000130) (000190)	IN 105-106 IN 105-106	1 2	1 1 0 0 67 27 40 35	0.8433	0.7713	0.9670
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 1 0 0		
Brain Lymphoma	(000130) (000270)	FA 102 FA 102	1 2	0 1 0 0 72 28 41 35	0.5932	0.4541	0.9237
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 0 0		
Epididymides Lipoma	(000160) (000240)	IN 105-106 IN 105-106	1 2	1 0 1 0 67 28 39 35	0.7123	0.6198	0.9193
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 1 0		
Epididymides Tumour (interstitial cell	(000160) (001003)	IN 105-106 IN 105-106	1 2	1 0 0 0 67 28 40 35	1.0000	0.8732	0.9964
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0		
Heart Sarcoma (neuro-)	(000200) (000405)	IN 105-106 IN 105-106	1 2	1 0 0 0 67 28 40 35	1.0000	0.8732	0.9964
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0		
Kidneys Carcinoma	(000250) (000140)	IN 105-106 IN 105-106	1 2	1 0 1 0 67 28 39 35	0.7123	0.6198	0.9193
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 1 0		
Kidneys Lipoma	(000250) (000240)	IN 92-104 IN 92-104	1 2	0 0 0 1 12 10 5 8	0.1824	0.1381	0.3792
		IN 105-106 IN 105-106	1 2	0 2 1 0 68 26 39 35			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 2 1 1		

Table 5a (Continued)

Liver	(000280)	IN 92-104	1	2	0	0	0	0.9914	0.9857	0.9973
Adenoma (hepatocellular)	(000103)	IN 92-104	2	10	10	5	9			
		IN 105-106	1	4	0	0	1			
		IN 105-106	2	64	28	40	34			
Spontaneous tumor pct: 6%		in ctrl. - Total	-	6	0	0	1			
Liver	(000280)	IN 92-104	1	0	1	0	0	0.2853	0.2377	0.4706
Lymphangioma	(000260)	IN 92-104	2	12	9	5	9			
		IN 105-106	1	1	1	2	1			
		IN 105-106	2	67	27	38	34			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	2	2	1			
Lungs	(000290)	IN 79-91	1	1	0	0	0	1.0000	0.9871	0.9987
Adenoma	(000100)	IN 79-91	2	11	6	2	4			
		IN 92-104	1	1	0	0	0			
		IN 92-104	2	11	10	5	9			
		IN 105-106	1	2	0	0	0			
		IN 105-106	2	66	28	40	35			
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4	0	0	0			
Lymph node (mandibular)	(000301)	IN 105-106	1	1	0	0	0	1.0000	0.8732	0.9964
Lymphoma	(000270)	IN 105-106	2	67	28	40	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Lymph node (mesenteric)	(000302)	IN 105-106	1	0	0	0	1	0.2047	0.0918	0.5851
Haemangioma	(000200)	IN 105-106	2	68	28	40	34			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1			
Lymph node (mesenteric)	(000302)	IN 92-104	1	0	1	0	0	0.6667	0.4930	0.9421
Lymphangioma	(000260)	IN 92-104	2	12	9	5	9			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	0	0			
Mammary gland	(000320)	IN 105-106	1	1	0	0	0	1.0000	0.8732	0.9964
Carcinoma	(000140)	IN 105-106	2	67	28	40	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Mammary gland	(000320)	IN 105-106	1	1	1	2	0	0.4813	0.4248	0.7223
Carcinoma (squamous cell)	(000145)	IN 105-106	2	67	27	38	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	2	0			
Mammary gland	(000320)	IN 105-106	1	1	0	0	0	1.0000	0.8732	0.9964
Fibroma (neuro-)	(000172)	IN 105-106	2	67	28	40	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Mammary gland	(000320)	IN 105-106	1	1	0	0	0	0.8379	0.7652	0.9654
Sarcoma	(000400)	IN 105-106	2	67	28	40	35			
		FA 100	1	0	1	0	0			
		FA 100	2	75	30	42	36			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	0			
Mesentery	(000330)	IN 105-106	1	0	0	1	0	0.4386	0.2383	0.7975
Lymphangioma	(000260)	IN 105-106	2	68	28	39	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			
Pancreas	(000380)	IN 92-104	1	1	0	0	0	1.0000	0.9906	0.9991
Adenoma	(000100)	IN 92-104	2	11	10	5	9			
		IN 105-106	1	3	0	0	0			
		IN 105-106	2	65	28	40	35			
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4	0	0	0			
Pancreas	(000380)	IN 53-78	1	0	1	0	0	0.5452	0.5212	0.6411
Insuloma	(000220)	IN 53-78	2	5	5	2	2			
		IN 79-91	1	2	1	0	0			
		IN 79-91	2	10	5	2	4			
		IN 92-104	1	1	1	0	0			
		IN 92-104	2	11	9	5	9			
		IN 105-106	1	7	6	6	4			
		IN 105-106	2	61	22	34	31			
Spontaneous tumor pct: 10%		in ctrl. - Total	-	10	9	6	4			

Table 5a (Continued)

Pancreas	(000380)	IN 105-106	1	0	0	1	0	0.4386	0.2383	0.7975
Lymphangioma	(000260)	IN 105-106	2	68	28	39	35			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	0			
Parathyroids	(000390)	IN 53-78	1	1	0	0	0	0.3184	0.2705	0.5173
Adenoma	(000100)	IN 53-78	2	4	6	2	2			
		IN 79-91	1	0	0	1	0			
		IN 79-91	2	12	6	1	4			
		IN 92-104	1	0	0	1	0			
		IN 92-104	2	12	10	4	9			
		IN 105-106	1	0	2	1	0			
		IN 105-106	2	68	26	39	35			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	2	3	0			
Pituitary	(000410)	IN 53-78	1	2	0	0	1	0.6411	0.6287	0.6899
Adenoma	(000100)	IN 53-78	2	1	3	0	1			
		IN 79-91	1	2	1	2	1			
		IN 79-91	2	3	0	0	0			
		IN 92-104	1	4	5	0	3			
		IN 92-104	2	3	1	1	1			
		IN 105-106	1	47	20	27	20			
		IN 105-106	2	21	8	13	15			
		FA 64	1	0	0	1	0			
		FA 64	2	97	50	48	50			
		FA 65	1	0	1	0	0			
		FA 65	2	96	49	48	49			
		FA 68	1	0	1	0	0			
		FA 68	2	96	47	48	49			
		FA 71	1	1	0	0	0			
		FA 71	2	94	46	48	49			
		FA 72	1	1	0	1	0			
		FA 72	2	93	46	47	49			
		FA 74	1	0	1	0	0			
		FA 74	2	92	45	47	49			
		FA 80	1	0	1	0	0			
		FA 80	2	89	43	47	48			
		FA 81	1	1	2	0	0			
		FA 81	2	88	41	47	48			
		FA 83	1	1	0	0	0			
		FA 83	2	87	41	47	48			
		FA 86	1	0	1	0	0			
		FA 86	2	87	40	47	48			
		FA 87	1	0	0	0	1			
		FA 87	2	86	40	47	46			
		FA 88	1	0	0	0	1			
		FA 88	2	86	40	47	45			
		FA 90	1	1	1	0	0			
		FA 90	2	84	38	45	45			
		FA 91	1	4	0	0	1			
		FA 91	2	80	38	45	44			
		FA 92	1	0	1	0	1			
		FA 92	2	80	37	45	43			
		FA 93	1	0	0	1	0			
		FA 93	2	79	36	44	42			
		FA 94	1	0	0	0	1			
		FA 94	2	78	36	44	40			
		FA 95	1	1	0	0	0			
		FA 95	2	77	36	44	40			
		FA 96	1	0	0	0	1			
		FA 96	2	77	36	44	38			
		FA 97	1	0	0	1	1			
		FA 97	2	77	36	42	37			
		FA 98	1	0	1	0	1			
		FA 98	2	75	35	42	36			
		FA 99	1	0	1	0	0			
		FA 99	2	75	33	42	36			

Table 5a (Continued)

		FA 100	1	1	0	1	0	
		FA 100	2	74	31	41	36	
		FA 101	1	0	1	0	0	
		FA 101	2	74	29	41	36	
		FA 102	1	1	0	0	0	
		FA 102	2	71	29	41	35	
		FA 103	1	2	0	1	0	
		FA 103	2	69	28	40	35	
Spontaneous tumor pct: 69%		in ctrl. - Total	-	69	38	35	33	
Pituitary	(000410)	FA 95	1	0	0	0	1	0.2020 0.0892 0.5834
Sarcoma	(000400)	FA 95	2	78	36	44	39	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
Prostate	(000430)	IN 92-104	1	0	1	0	0	0.5417 0.4523 0.7830
Adenoma	(000100)	IN 92-104	2	12	9	5	9	
		IN 105-106	1	1	0	0	1	
		IN 105-106	2	67	28	40	34	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	1	
Prostate	(000430)	IN 79-91	1	1	0	0	0	1.0000 0.8193 0.9942
Carcinoma	(000140)	IN 79-91	2	11	6	2	4	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
Peritoneum	(000450)	IN 105-106	1	0	1	2	0	0.2429 0.1891 0.5063
Lymphangioma	(000260)	IN 105-106	2	68	27	38	35	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	2	0	
Salivary gland	(000480)	IN 105-106	1	1	0	0	0	1.0000 0.9732 0.9964
Carcinoma (squamous cell)	(000143)	IN 105-106	2	67	28	40	35	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
Seminal vesicle	(000490)	IN 92-104	1	0	0	1	0	0.3889 0.2566 0.8255
Carcinoma	(000140)	IN 92-104	2	12	10	4	9	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
Skin	(000510)	IN 92-104	1	0	1	0	0	0.8674 0.7901 0.9722
Adenoma	(000100)	IN 92-104	2	12	9	5	9	
		IN 105-106	1	1	0	0	0	
		IN 105-106	2	67	28	40	35	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	0	
Skin	(000510)	IN 105-106	1	0	0	1	0	0.4386 0.2383 0.7975
Carcinoma	(000140)	IN 105-106	2	68	28	39	35	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
Uterus	(000510)	IN 53-78	1	1	0	0	0	0.8690 0.8528 0.9263
Carcinoma squamous cell)	(000143)	IN 53-78	2	4	6	2	2	
		IN 92-104	1	1	0	0	0	
		IN 92-104	2	11	10	4	9	
		IN 105-106	1	6	2	4	0	
		IN 105-106	2	62	26	36	35	
		FA 86	1	0	0	0	1	
		FA 86	2	87	41	47	47	
		FA 96	1	0	0	1	0	
		FA 96	2	77	36	43	39	
Spontaneous tumor pct: 8%		in ctrl. - Total	-	8	2	5	1	
Skin	(000510)	IN 92-104	1	0	0	0	1	0.2500 0.0985 0.6181
Fibroma (neuro-)	(000172)	IN 92-104	2	12	10	5	8	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
Skin	(000510)	IN 105-106	1	0	0	0	2	0.0409 0.0297 0.2146
Lipoma	(000240)	IN 105-106	2	68	28	40	33	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	2	

Table 5a (Continued)

Skin	(000510)	IN 105-106	1	0	1	0	0	0.6023	0.4626	0.9265
Lipoma (fibro-)	(000241)	IN 105-106	2	68	27	40	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0			
Skin	(000510)	IN 92-104	1	0	0	0	1	0.2684	0.1670	0.5564
Papilloma	(000300)	IN 92-104	2	12	10	5	8			
		IN 105-106	1	0	1	0	0			
		IN 105-106	2	68	27	40	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	1			
Skin	(000510)	IN 79-91	1	1	0	0	0	0.9120	0.8881	0.9683
Sarcoma	(000400)	IN 79-91	2	11	6	2	4			
		IN 92-104	1	0	0	0	1			
		IN 92-104	2	12	9	5	8			
		IN 105-106	1	3	0	0	0			
		IN 105-106	2	65	28	40	35			
		FA 98	1	0	1	0	0			
		FA 98	2	75	35	42	37			
Spontaneous tumor pct: 4% in ctrl.	-	Total	-	4	1	0	1			
Skin	(000510)	IN 105-106	1	0	0	1	0	0.4386	0.2383	0.7975
Sarcoma (fibro-)	(000403)	IN 105-106	2	68	28	39	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	0			
Spleen	(000530)	IN 105-106	1	0	0	1	0	0.4386	0.2383	0.7975
Haemangioma	(000200)	IN 105-106	2	68	28	39	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	0			
Spleen	(000530)	FA 101	1	1	0	0	0	1.0000	0.6678	0.9961
Splenoma	(000440)	FA 101	2	73	30	41	36			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Stomach	(000550)	IN 92-104	1	0	0	0	1	0.2500	0.0985	0.6181
Myoma	(000280)	IN 92-104	2	12	10	5	8			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	0	1			
Testicles	(000560)	IN 92-104	1	0	0	0	1	0.9232	0.9102	0.9642
Tumour (interstitial cell)	(001003)	IN 92-104	2	12	10	5	8			
		IN 105-106	1	7	1	3	0			
		IN 105-106	2	61	27	37	35			
Spontaneous tumor pct: 7% in ctrl.	-	Total	-	7	1	3	1			
Testicles	(000560)	IN 92-104	1	0	1	0	0	0.6667	0.4930	0.9421
Tumour (Sertoli-cell-)	(001004)	IN 92-104	2	12	9	5	9			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0			
Thymus	(000590)	IN 105-106	1	1	0	0	0	1.0000	0.8732	0.9964
Haemangioma	(000200)	IN 105-106	2	67	28	40	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Thymus	(000590)	IN 105-106	1	0	0	1	0	0.4386	0.2383	0.7975
Lymphoma	(000270)	IN 105-106	2	68	28	39	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	0			
Thymus	(000590)	IN 79-91	1	1	0	0	0	1.0000	0.8193	0.9942
Sarcoma	(000400)	IN 79-91	2	11	6	2	4			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Thyroids	(000610)	IN 79-91	1	1	0	0	0	0.9100	0.8974	0.9513
Adenoma	(000100)	IN 79-91	2	11	6	2	4			
		IN 92-104	1	0	1	0	0			
		IN 92-104	2	12	9	5	9			
		IN 105-106	1	9	1	1	4			
		IN 105-106	2	59	27	39	31			
Spontaneous tumor pct: 10% in ctrl.	-	Total	-	10	2	1	4			

Table 5a (Continued)

Thyroids	(000610)	IN 105-106	1	0	0	0	1	0.2517	0.1515	0.5272
Carcinoma	(000140)	IN 105-106	2	68	28	40	34			
		FA 99	1	0	1	0	0			
		FA 99	2	75	33	42	36			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	1			
Localisation unknown	(001000)	IN 105-106	1	1	0	0	0	1.0000	0.8732	0.9964
Carcinoma	(000140)	IN 105-106	2	67	28	40	35			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Multiple Organs	(001100)	FA 30	1	1	0	0	0	0.6377	0.5913	0.8075
Leukaemia	(000230)	FA 30	2	99	50	50	50			
		FA 64	1	1	0	0	1			
		FA 64	2	96	50	49	49			
		FA 65	1	0	1	0	0			
		FA 65	2	96	49	48	49			
		FA 79	1	1	0	0	0			
		FA 79	2	91	44	47	48			
		FA 95	1	0	0	0	1			
		FA 95	2	78	36	44	39			
Spontaneous tumor pct: 3% in ctrl.		- Total	-	3	1	0	2			

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Table 5b

Analysis of Carcinogenic Potential in Female Rat
 Test of Dose-Response (Tumor) Positive Linear Trend

Dose Levels Included: CTRL LOW MED HIGH (0 0.4 0.6 0.8)
 Missing value in Tumor-Caused Death is treated as tumor not causing death
 Tumor type: IN: Incidental (nonfatal) tumor, FA: Fatal tumor.

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLE-----	EXACT PROB	ASYMP TOTIC	ASYMP (CONTI NUITY CORR)
Adrenals	(000100)	IN 79-91	1	1 0 0 0			
Adenoma	(000100)	IN 79-91	2	12 6 7 2			
		IN 92-104	1	0 0 1 1			
		IN 92-104	2	14 5 5 5			
		IN 105-106	1	8 2 3 1			
		IN 105-106	2	56 32 28 34			
		FA 99	1	0 1 0 0			
		FA 99	2	70 38 35 39			
Spontaneous tumor pct: 9%		in ctrl. - Total	-	9 3 4 2			
Adrenals	(000100)	IN 105-106	1	0 0 1 0	0.4024	0.2341	0.7973
Lipoma	(000240)	IN 105-106	2	64 34 30 35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 0 1 0			
Adrenals	(000100)	IN 105-106	1	0 0 1 0	0.4024	0.2341	0.7973
Lymphangioma	(000260)	IN 105-106	2	64 34 30 35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 0 1 0			
Brain	(000130)	IN 105-106	1	0 1 0 0	0.6098	0.4592	0.9272
Ependymoma	(000160)	IN 105-106	2	64 33 31 35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0			
Brain	(000130)	FA 57	1	0 1 0 0	0.5959	0.4451	0.9234
Glioma	(000190)	FA 57	2	99 49 48 48			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0			
Brain	(000130)	FA 80	1	0 1 0 0	0.5928	0.4413	0.9223
Lymphoma	(000270)	FA 80	2	90 45 42 43			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0			
Brain	(000130)	IN 105-106	1	2 0 0 0	1.0000	0.9476	0.9969
Papilloma	(000300)	IN 105-106	2	62 34 31 35			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2 0 0 0			
Caecum	(000140)	IN 105-106	1	0 0 0 1	0.2134	0.0887	0.5827
Lymphangioma	(000260)	IN 105-106	2	64 34 31 34			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 0 0 1			
Kidneys	(000250)	IN 105-106	1	0 1 0 0	0.6098	0.4592	0.9272
Lipoma	(000240)	IN 105-106	2	64 33 31 35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0			
Kidneys	(000250)	IN 105-106	1	1 0 0 0	1.0000	0.8736	0.9965
Papilloma	(000300)	IN 105-106	2	63 34 31 35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1 0 0 0			
Liver	(000280)	IN 79-91	1	0 0 0 1	0.1473	0.1117	0.3067
Adenoma (hepatocellular)	(000103)	IN 79-91	2	13 6 7 1			
		IN 105-106	1	0 1 1 1			
		IN 105-106	2	64 33 30 34			
		FA 74	1	1 0 0 0			
		FA 74	2	96 46 45 46			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1 1 1 2			

Table 5b (Continued)

Liver	(000280)	FA 88	1	1	0	0	0	1.0000	0.8688	0.9964
Carcinoma	(000140)	FA 88	2	82	43	40	41			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	1	0	0	0			
Liver	(000280)	IN 79-91	1	0	1	0	0	0.5357	0.3560	0.9121
Haemangioma	(000200)	IN 79-91	2	13	5	7	2			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	0	1	0	0			
Liver	(000280)	IN 105-106	1	1	0	1	0	0.6864	0.6165	0.9194
Lymphangioma	(000260)	IN 105-106	2	63	34	30	35			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	1	0	1	0			
Lungs	(000290)	IN 53-78	1	1	0	0	0	1.0000	0.8878	0.9972
Carcinoma (adeno-)	(000141)	IN 53-78	2	7	4	5	5			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	1	0	0	0			
Lymph node (mandibular)	(000301)	IN 53-78	1	0	0	1	0	0.4545	0.2579	0.8170
Lymphoma	(000270)	IN 53-78	2	8	4	4	5			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	0	0	1	0			
Lymph node (mandibular)	(000301)	FA 74	1	1	0	0	0	1.0000	0.8630	0.9960
Sarcoma	(000400)	FA 74	2	96	46	45	46			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	1	0	0	0			
Lymph node (mesenteric)	(000302)	IN 105-106	1	0	0	1	0	0.2510	0.1526	0.5312
Lymphangioma	(000260)	IN 105-106	2	64	34	30	35			
		FA 103	1	0	0	1	0			
		FA 103	2	66	36	32	36			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	0	0	2	0			
Mammary gland	(000320)	IN 53-78	1	0	0	0	1	0.9705	0.9611	0.9892
Adenoma	(000100)	IN 53-78	2	8	4	5	4			
		IN 92-104	1	3	0	0	1			
		IN 92-104	2	10	6	6	5			
		IN 105-106	1	3	0	0	0			
		IN 105-106	2	61	34	31	35			
		FA 100	1	1	0	0	0			
		FA 100	2	68	37	35	39			
Spontaneous tumor pct:	7%	in ctrl. - Total	-	7	0	0	2			
Mammary gland	(000320)	IN 92-104	1	0	0	0	1	0.0595	0.0467	0.1318
Adenoma (fibro-)	(000102)	IN 92-104	2	14	6	6	5			
		IN 105-106	1	1	2	1	1			
		IN 105-106	2	63	32	30	34			
		FA 74	1	0	0	0	1			
		FA 74	2	97	46	45	45			
		FA 90	1	0	0	1	0			
		FA 90	2	78	42	38	41			
Spontaneous tumor pct:	<= 1% in ctrl. - Total		-	1	2	2	3			
Mammary gland	(000320)	IN 105-106	1	8	6	3	2	0.7176	0.6977	0.7981
Carcinoma	(000140)	IN 105-106	2	56	28	29	33			
		FA 68	1	0	0	1	0			
		FA 68	2	99	47	46	46			
		FA 79	1	0	0	1	0			
		FA 79	2	91	46	43	43			
		FA 88	1	1	0	0	0			
		FA 88	2	62	43	40	41			
		FA 92	1	1	0	0	0			
		FA 92	2	77	40	37	41			
		FA 94	1	0	0	0	1			
		FA 94	2	73	39	37	39			
		FA 102	1	0	0	1	0			
		FA 102	2	66	36	34	36			
		FA 103	1	1	1	1	0			
		FA 103	2	65	35	32	36			
Spontaneous tumor pct:	11%	in ctrl. - Total	-	11	7	7	3			

Table 5b (Continued)

Mammary gland	(000320)	IN 105-106	1	2	0	0	0	0.9418	0.8976	0.9850
Carcinoma (adeno-)	(000141)	IN 105-106	2	62	34	31	35			
		FA 103	1	0	1	0	0			
		FA 103	2	66	35	33	36			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	1	0	0			
Mammary gland	(000320)	IN 105-106	1	2	0	0	0	0.8460	0.8163	0.9644
Fibroma (adeno-)	(000171)	IN 105-106	2	62	34	31	35			
		FA 90	1	0	0	1	0			
		FA 90	2	78	42	38	41			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	1	0			
Mammary gland	(000320)	IN 105-106	1	1	1	0	0	0.8492	0.7698	0.9673
Lipoma	(000240)	IN 105-106	2	63	33	31	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	0			
Mammary gland	(000320)	FA 73	1	1	0	0	0	0.6785	0.6044	0.9145
Sarcoma	(000400)	FA 73	2	97	46	46	46			
		FA 96	1	0	0	1	0			
		FA 96	2	72	39	36	39			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	1	0			
Mammary gland	(000320)	IN 105-106	1	1	0	0	0	1.0000	0.8736	0.9965
Tumour (general., mastopa	(001001)	IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Ovaries	(000370)	IN 92-104	1	2	0	0	0	0.9284	0.8761	0.9819
Luteoma	(000250)	IN 92-104	2	12	6	6	6			
		IN 105-106	1	0	1	0	0			
		IN 105-106	2	64	33	31	35			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	1	0	0			
Ovaries	(000370)	IN 79-91	1	1	0	0	1	0.5244	0.4812	0.6996
Tumour (granulosa cell-)	(001002)	IN 79-91	2	12	6	7	1			
		IN 92-104	1	0	0	1	0			
		IN 92-104	2	14	6	5	6			
		IN 105-106	1	2	2	1	0			
		IN 105-106	2	62	32	30	35			
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3	2	2	1			
Pancreas	(000380)	IN 105-106	1	1	1	0	0	0.8492	0.7698	0.9673
Adenoma	(000100)	IN 105-106	2	63	33	31	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	0			
Pancreas	(000380)	IN 92-104	1	0	0	0	1	0.3831	0.3472	0.5278
Insulinoma	(000220)	IN 92-104	2	14	6	6	5			
		IN 105-106	1	4	3	2	2			
		IN 105-106	2	60	31	29	33			
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4	3	2	3			
Parathyroids	(000390)	IN 92-104	1	0	1	0	0	0.3041	0.2579	0.6736
Adenoma	(000100)	IN 92-104	2	14	5	6	6			
		IN 105-106	1	0	0	1	0			
		IN 105-106	2	64	34	30	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	1	0			
Parathyroid	(000410)	IN 0-52	1	0	0	0	1	0.9680	0.9654	0.9763
Adenoma	(000100)	IN 0-52	2	0	0	1	1			
		IN 53-78	1	1	1	1	0			
		IN 53-78	2	2	0	1	1			
		IN 79-91	1	2	0	3	0			
		IN 79-91	2	1	1	0	1			
		IN 92-104	1	2	2	1	1			
		IN 92-104	2	1	1	2	0			
		IN 105-106	1	54	29	25	25			
		IN 105-106	2	9	5	6	10			
		FA 47	1	1	0	0	0			
		FA 47	2	99	50	50	49			

Table 5b (Continued)

FA 56	1	0	0	1	0
FA 56	2	99	50	48	48
FA 57	1	0	1	0	0
FA 57	2	99	49	48	48
FA 58	1	0	1	0	0
FA 58	2	99	48	48	48
FA 66	1	0	0	0	2
FA 66	2	99	47	47	46
FA 70	1	1	1	0	0
FA 70	2	98	46	46	46
FA 73	1	0	0	1	0
FA 73	2	98	46	45	46
FA 74	1	1	0	0	0
FA 74	2	96	46	45	46
FA 75	1	1	0	0	1
FA 75	2	95	46	45	44
FA 76	1	0	0	0	1
FA 76	2	95	46	45	43
FA 77	1	2	0	1	0
FA 77	2	92	46	44	43
FA 79	1	1	0	2	0
FA 79	2	90	46	42	43
FA 80	1	1	1	0	0
FA 80	2	89	45	42	43
FA 81	1	0	1	0	0
FA 81	2	89	43	42	43
FA 82	1	1	0	0	0
FA 82	2	88	43	42	43
FA 83	1	2	0	0	0
FA 83	2	86	43	42	43
FA 84	1	1	0	0	0
FA 84	2	85	43	42	43
FA 86	1	1	0	0	0
FA 86	2	84	43	42	43
FA 87	1	0	0	1	1
FA 87	2	83	43	40	41
FA 88	1	2	0	0	0
FA 88	2	81	43	40	41
FA 89	1	1	1	1	0
FA 89	2	78	42	39	41
FA 91	1	0	2	0	0
FA 91	2	78	40	38	41
FA 92	1	4	1	0	0
FA 92	2	74	39	37	41
FA 94	1	0	0	0	1
FA 94	2	73	39	37	39
FA 96	1	1	0	0	0
FA 96	2	71	39	37	39
FA 97	1	1	0	0	0
FA 97	2	70	39	36	39
FA 98	1	0	0	1	0
FA 98	2	70	39	35	39
FA 99	1	1	2	0	0
FA 99	2	69	37	35	39
FA 100	1	1	0	0	3
FA 100	2	68	37	35	36
FA 101	1	1	0	0	0
FA 101	2	66	37	35	36
FA 102	1	0	0	2	0
FA 102	2	66	36	33	36
FA 103	1	1	0	0	0
FA 103	2	65	36	33	36
FA 104	1	1	0	0	1
FA 104	2	64	34	32	35
FA 106	1	1	0	0	0
FA 106	2	26	13	11	13
Spontaneous tumor pct: 87%	in ctrl.	-	Total	-	87 43 40 37

Table 5b (Continued)

Salivary gland	(000480)	IN 105-106	1	1	0	0	0	1.0000	0.8736	0.9965
Carcinoma	(000140)	IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Skin	(000510)	IN 105-106	1	1	0	0	0	1.0000	0.8736	0.9965
Adenoma	(000100)	IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Skin	(000510)	IN 79-91	1	1	0	0	0	1.0000	0.8435	0.9969
Adenoma (fibro-)	(000102)	IN 79-91	2	12	6	7	2			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Skin	(000510)	IN 105-106	1	3	0	2	0	0.6026	0.5611	0.7611
Carcinoma	(000140)	IN 105-106	2	61	34	29	35			
		FA 87	1	0	0	1	0			
		FA 87	2	83	43	40	42			
		FA 98	1	0	0	1	0			
		FA 98	2	70	39	35	39			
		FA 99	1	0	1	0	0			
		FA 99	2	70	38	35	39			
Spontaneous tumor pct: 3% in ctrl.	-	Total	-	3	1	4	0			
Skin	(000510)	FA 76	1	1	0	0	0	1.0000	0.9883	0.9989
Carcinoma (adeno-)	(000141)	FA 76	2	94	46	45	44			
		FA 88	1	1	0	0	0			
		FA 88	2	82	43	40	41			
		FA 97	1	1	0	0	0			
		FA 97	2	70	39	36	39			
		FA 100	1	1	0	0	0			
		FA 100	2	68	37	35	39			
Spontaneous tumor pct: 4% in ctrl.	-	Total	-	4	0	0	0			
Skin	(000510)	IN 105-106	1	2	0	0	0	1.0000	0.9884	0.9989
Carcinoma (squamous cell)	(000143)	IN 105-106	2	62	34	31	35			
		FA 86	1	1	0	0	0			
		FA 86	2	84	43	42	43			
		FA 88	1	1	0	0	0			
		FA 88	2	82	43	40	41			
Spontaneous tumor pct: 4% in ctrl.	-	Total	-	4	0	0	0			
Skin	(000510)	IN 105-106	1	1	0	0	0	1.0000	0.8736	0.9965
Fibroma (neuro-)	(000172)	IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0			
Skin	(000510)	IN 79-91	1	1	0	0	0	0.9207	0.8660	0.9791
Lipoma	(000240)	IN 79-91	2	12	6	7	2			
		IN 92-104	1	0	1	0	0			
		IN 92-104	2	14	5	6	6			
		IN 105-106	1	1	0	0	0			
		IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	1	0	0			
Skin	(000510)	IN 92-104	1	0	1	0	0	0.5625	0.4230	0.9130
Capilloma	(000300)	IN 92-104	2	14	5	6	6			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0			
Spleen	(000530)	IN 105-106	1	0	0	0	1	0.2134	0.0887	0.5827
Leukocytoma	(000210)	IN 105-106	2	64	34	31	34			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	0	1			
Sternum	(000540)	FA 98	1	0	0	1	0	0.4076	0.2372	0.8028
Carcinoma	(000140)	FA 98	2	70	39	35	39			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	0			
Thymus	(000590)	IN 105-106	1	0	0	2	0	0.2495	0.1517	0.5301
Thymoma	(000460)	IN 105-106	2	64	34	29	35			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	2	0			

Table 5b (Continued)

Thyroids	(000610)	IN 79-91	1	1	0	0	0	0.6347	0.5970	0.7825
Adenoma	(000100)	IN 79-91	2	12	6	7	2			
		IN 105-106	1	3	2	1	2			
		IN 105-106	2	61	32	30	33			
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4	2	1	2			
Uterus	(000650)	IN 53-78	1	1	0	0	0	1.0000	0.8878	0.9972
Adenoma (fibro-)	(000102)	IN 53-78	2	7	4	5	5			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Uterus	(000650)	FA 88	1	1	0	0	0	1.0000	0.8688	0.9964
Carcinoma	(000140)	FA 88	2	82	43	40	41			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Uterus	(000650)	FA 101	1	1	0	0	0	1.0000	0.8770	0.9969
Carcinoma (adeno-)	(000141)	FA 101	2	66	37	35	36			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Uterus	(000650)	IN 105-106	1	0	0	1	0	0.4024	0.2341	0.7973
Carcinoma (squamous cell)	(000143)	IN 105-106	2	64	34	30	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			
Uterus	(000650)	IN 105-106	1	1	0	0	0	1.0000	0.8736	0.9965
Fibroma (adeno-)	(000171)	IN 105-106	2	63	34	31	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Uterus	(000650)	FA 86	1	0	0	1	0	0.3962	0.2264	0.7909
Sarcoma (angio-)	(000401)	FA 86	2	85	43	40	43			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			
Uterine region	(000651)	IN 92-104	1	0	1	0	0	0.2108	0.1564	0.4576
Carcinoma (squamous cell)	(000143)	IN 92-104	2	14	5	6	6			
		FA 77	1	0	0	1	0			
		FA 77	2	94	46	44	43			
		FA 79	1	0	0	1	0			
		FA 79	2	91	46	43	43			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	2	0			
Localisation unknown	(001000)	IN 53-78	1	1	0	0	0	1.0000	0.8878	0.9972
Carcinoma	(000140)	IN 53-78	2	7	4	5	5			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Localisation unknown	(001000)	IN 105-106	1	0	0	0	1	0.2134	0.0887	0.5827
Fibroma (adeno-)	(000171)	IN 105-106	2	64	34	31	34			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1			
Localisation unknown	(001000)	FA 63	1	0	1	0	0	0.5909	0.4437	0.9218
Undifferentiated cell mal	(0001100)	FA 63	2	99	47	47	48			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	0	0			
Multiple Organs	(001100)	FA 68	1	0	0	1	0	0.3891	0.2180	0.7831
Leukaemia	(000230)	FA 68	2	99	47	46	46			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			

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Table 6a

Number of Animals
Species: Mouse
Sex: Male

	Treatment Group				Total
	CTRL	LOW	MED	HIGH	
	Count	Count	Count	Count	
Time Interval					
0-52	1	3	5	5	14
53-78	17	6	9	6	38
79-91	16	6	13	8	43
92-104	26	12	8	13	59
105-105	40	23	15	19	97
Total	100	50	50	51	251

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Table 6b

Number of Animals
Species: Mouse
Sex: Female

	Treatment Group				Total
	CTRL	LOW	MED	HIGH	
	Count	Count	Count	Count	Count
Time Interval					
0-52	9	4	1	2	16
53-78	25	11	18	17	71
79-91	26	15	13	12	66
92-99	15	8	9	5	37
100-100	25	12	9	13	59
Total	100	50	50	49	249

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Table 7a

Analysis of Mortality
 Species: Mouse
 Sex: Male

	Dose											
	CTRL			LOW			MED			HIGH		
	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died
Time (wks)												
0-52	1	100	1.0	3	50	6.0	5	50	10.0	5	51	9.8
53-78	17	99	18.0	6	47	18.0	9	45	28.0	6	46	21.6
79-91	16	82	34.0	6	41	30.0	13	36	54.0	8	40	37.3
92-104	26	66	60.0	12	35	54.0	8	23	70.0	13	32	62.7
105-105	40	100	40.0	23	50	46.0	15	50	30.0	19	51	37.3

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Table 7b

Analysis of Mortality
 Species: Mouse
 Sex: Female

	Dose											
	CTRL			LOW			MED			HIGH		
	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died	Num. of Dead	Num. at Risk	Cumu Pct. Died
Time (-wks)												
0-52	9	100	9.0	4	50	8.0	1	50	2.0	2	49	4.1
53-78	25	91	34.0	11	46	30.0	18	49	38.0	17	47	38.8
79-91	26	66	60.0	15	35	60.0	13	31	64.0	12	30	63.3
92-99	15	40	75.0	8	20	78.0	9	18	82.0	5	18	73.5
100-100	25	100	25.0	12	50	24.0	9	50	18.0	13	49	26.5

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Table 8a

Dose-Mortality Trend Tests

This test is run using Trend and Homogeneity Analyses of Proportions and Life Table Data Version 2.1, by Donald G. Thomas, National Cancer Institute

Species: Mouse

Sex: Male

Method	Time-Adjusted Trend Test	Statistic	P Value
Cox	Dose-Mortality Trend	0.89	0.3468
	Depart from Trend	4.27	0.1180
	Homogeneity	5.16	0.1605
Kruskal-Wallis	Dose-Mortality Trend	1.34	0.2462
	Depart from Trend	5.16	0.0759
	Homogeneity	6.50	0.0896

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Table 8b

Dose-Mortality Trend Tests

This test is run using Trend and Homogeneity Analyses of Proportions and Life Table Data Version 2.1, by Donald G. Thomas, National Cancer Institute

Species: Mouse
Sex: Female

Method	Time-Adjusted Trend Test	Statistic	P Value
Cox	Dose-Mortality Trend	0.11	0.7392
	Depart from Trend	0.38	0.8254
	Homogeneity	0.49	0.9201
Kruskal-Wallis	Dose-Mortality Trend	0.24	0.6225
	Depart from Trend	0.22	0.8976
	Homogeneity	0.46	0.9279

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Table 9 (Part I)

Organs and Organ Codes (Mouse)

000100 Adrenals--
000110 Anus
000130 Brain
000160 Epididymides
000190 Harder's gland
000220 Intestine (large)
000280 Liver
000290 Lungs
000302 Lymph node (mesenteric)
000330 Mesentery
000350 Optic region
000370 Ovaries
000380 Pancreas
000390 Parathyroids
000400 Penis
000410 Pituitary
000420 Preputial gland
000480 Salivary gland
000490 Seminal vesicle
000510 Skin
000520 Spinal cord
000530 Spleen
000550 Stomach
000560 Testicles
000590 Thymus
000610 Thyroids
000630 Urinary bladder
000650 Uterus
000651 Uterine region
001000 Localisation unknown
001100 Multiple Organs

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Table 9 (Part II)

-- Tumors and Tumor Codes (Mouse)

000090 Adenocarcinoid
000100 Adenoma
000101 Adenoma (cyst-)
000103 Adenoma (hepatocellular)
000130 Angioma
000140 Carcinoma
000141 Carcinoma (adeno-)
000142 Carcinoma (hepatocellular)
000143 Carcinoma (squamous cell)
000160 Ependymoma
000171 Fibroma (adeno-)
000190 Glioma
000200 Haemangioma
000210 Histiocytoma
000220 Insuloma
000230 Leukaemia
000240 Lipoma
000260 Lymphangioma
000270 Lymphoma
000280 Myoma
000300 Papilloma
000320 Polyp
000400 Sarcoma
000401 Sarcoma (angio-)
000402 Sarcoma (carcino-)
000404 Sarcoma (leiomyo-)
000430 Seminoma
000460 Thymoma
001002 Tumour (granulosa cell-)
001003 Tumour (interstitial cell-)

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Table 10a
Analysis of Carcinogenic Potential in Male Mouse
Test of Dose-Response (Tumor) Positive Linear Trend

Dose Levels Included: CTRL LOW MED HIGH (0 2 4 8)
 Missing value in Tumor-Caused Death is treated as tumor not causing death
 Tumor Type: IN: Incidental (nonfatal) tumor, FA: Fatal tumor.

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY TABLE	EXACT PROB	ASYMP TOTIC	ASYMP (CONTI NUITY CORR)
Adrenals	(000100)	IN 53-78	1	0 0 0 1			
Adenoma	(000100)	IN 53-78	2	17 6 9 5			
		IN 92-104	1	1 0 0 1			
		IN 92-104	2	25 12 8 12			
		IN 105-105	1	6 4 3 4			
		IN 105-105	2	34 19 12 15			
Spontaneous tumor pct: 7%	in ctrl.	- Total	-	7 4 3 6			0.1340 0.1153 0.1234
Adrenals	(000100)	IN 92-104	1	1 0 0 0	1.0000	0.8934	0.9132
Carcinoma	(000140)	IN 92-104	2	25 12 8 13			
		IN 105-105	1	1 0 0 0			
		IN 105-105	2	39 23 15 19			
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2 0 0 0			
Adrenals	(000100)	IN 92-104	1	0 0 1 0	0.6299	0.6247	0.6678
Lymphoma	(000270)	IN 92-104	2	26 12 7 13			
		IN 105-105	1	1 0 0 0			
		IN 105-105	2	39 23 15 19			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1 0 1 0			
Anus	(000110)	FA 100	1	0 1 0 0	0.5565	0.5746	0.6386
Sarcoma	(000400)	FA 100	2	55 26 19 24			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0 1 0 0			
Epididymides	(000160)	IN 92-104	1	0 1 0 0	0.1959	0.1417	0.1693
Sarcoma	(000400)	IN 92-104	2	26 11 8 13			
		IN 105-105	1	0 0 0 1			
		IN 105-105	2	40 23 15 18			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0 1 0 1			
Harder's gland	(000190)	IN 79-91	1	1 0 0 0	0.8532	0.8279	0.8419
Adenoma	(000100)	IN 79-91	2	15 6 13 8			
		IN 92-104	1	0 2 0 0			
		IN 92-104	2	26 10 8 13			
		IN 105-105	1	3 2 0 1			
		IN 105-105	2	37 21 15 18			
Spontaneous tumor pct: 4%	in ctrl.	- Total	-	4 4 0 1			
Liver	(000280)	IN 92-104	1	1 0 0 0	1.0000	0.8077	0.8484
Adenoma	(000100)	IN 92-104	2	25 12 8 13			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1 0 0 0			
Liver	(000280)	IN 92-104	1	0 1 0 0	0.5773	0.5523	0.5728
Adenoma (hepatocellular)	(000103)	IN 92-104	2	25 11 8 13			
		IN 105-105	1	5 1 0 3			
		IN 105-105	2	35 22 15 16			
		FA 100	1	1 0 0 0			
		FA 100	2	54 27 18 24			
Spontaneous tumor pct: 6%	in ctrl.	- Total	-	6 2 0 3			
Liver	(000280)	IN 92-104	1	0 1 0 0	0.5593	0.5903	0.6512
Angioma	(000130)	IN 92-104	2	26 11 8 13			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0 1 0 0			
Liver	(000280)	FA 96	1	1 0 0 0	1.0000	0.8065	0.8480
Carcinoma (hepatocellular)	(000142)	FA 96	2	59 31 18 29			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1 0 0 0			

Table 10a (Continued)

Liver	(000280)	IN 53-78	1	0	0	0	1			
Haemangioma	(000200)	IN 53-78	2	17	6	9	5	0.2614	0.2286	0.2470
		IN 79-91	1	0	0	0	1			
		IN 79-91	2	15	6	12	7			
		IN 105-105	1	1	1	1	0			
		IN 105-105	2	39	22	14	19			
		FA 79	1	0	0	1	0			
		FA 79	2	82	41	35	40			
		FA 84	1	1	0	0	0			
		FA 84	2	76	37	31	38			
		FA 93	1	0	1	0	0			
		FA 93	2	62	34	22	32			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	2	2	2			
Liver	(000280)	IN 105-105	1	0	0	1	0	0.3505	0.3265	0.3890
Leukaemia	(000230)	IN 105-105	2	40	23	14	19			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			
Lungs	(000290)	IN 0-52	1	0	0	1	0	0.5746	0.5611	0.5711
Adenoma	(000100)	IN 0-52	2	1	3	4	5			
		IN 92-104	1	2	0	0	1			
		IN 92-104	2	20	11	6	10			
		IN 105-105	1	11	5	4	4			
		IN 105-105	2	29	18	11	15			
		FA 66	1	0	0	0	1			
		FA 66	2	95	44	40	43			
		FA 67	1	1	0	0	0			
		FA 67	2	94	44	40	43			
		FA 70	1	0	0	2	0			
		FA 70	2	92	42	38	43			
		FA 73	1	0	1	0	0			
		FA 73	2	88	41	37	41			
		FA 78	1	1	0	0	0			
		FA 78	2	82	41	37	40			
		FA 80	1	1	0	0	0			
		FA 80	2	80	40	35	39			
		FA 82	1	0	0	1	0			
		FA 82	2	78	38	33	38			
		FA 84	1	0	0	1	0			
		FA 84	2	77	37	30	38			
		FA 85	1	1	0	0	0			
		FA 85	2	74	37	29	38			
		FA 87	1	0	0	0	1			
		FA 87	2	70	36	28	35			
		FA 91	1	1	0	0	0			
		FA 91	2	66	35	24	33			
		FA 92	1	2	0	0	0			
		FA 92	2	64	35	23	32			
		FA 93	1	0	0	1	0			
		FA 93	2	62	35	21	32			
		FA 98	1	0	0	0	1			
		FA 98	2	58	30	18	26			
		FA 99	1	0	1	0	1			
		FA 99	2	57	27	18	24			
		FA 101	1	1	0	0	0			
		FA 101	2	49	26	18	22			
		FA 103	1	0	0	1	0			
		FA 103	2	44	26	15	22			
		FA 104	1	1	0	0	0			
		FA 104	2	41	25	15	20			
Spontaneous tumor pct: 22%		in ctrl. - Total	-	22	7	11	9			
Lungs	(000290)	FA 80	1	0	1	0	0	0.4632	0.4469	0.4936
Carcinoma	(000140)	FA 80	2	81	39	35	39			
		FA 103	1	0	0	1	0			
		FA 103	2	44	26	15	22			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	1	0			

Table 10a (Continued)

Lymph node (mesenteric)	(000302)	IN 53-78	1	1	0	0	0	0.7679	0.7353	0.7574
Lymphoma	(000270)	IN 53-78	2	16	6	9	6			
		IN 79-91	1	0	0	2	0			
		IN 79-91	2	16	6	11	8			
		IN 92-104	1	1	0	1	0			
		IN 92-104	2	25	12	7	13			
		IN 105-105	1	1	0	0	0			
		IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3	0	3	0			
Mesentery	(000330)	IN 0-52	1	0	0	0	1	0.3571	0.1104	0.1497
Lymphoma	(000270)	IN 0-52	2	1	3	5	4			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1			
Optic region	(000350)	FA 73	1	0	1	0	0	0.5769	0.5912	0.6543
Carcinoma	(000140)	FA 73	2	88	41	37	41			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	0	0			
Pancreas	(000380)	IN 105-105	1	3	2	0	0	0.9572	0.9230	0.9334
Insuloma	(000220)	IN 105-105	2	37	21	15	19			
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3	2	0	0			
Penis	(000400)	IN 79-91	1	0	0	1	0	0.4884	0.3623	0.4285
Adenoma	(000100)	IN 79-91	2	16	6	12	8			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0			
Penis	(000400)	IN 105-105	1	0	0	0	1	0.1959	0.0366	0.0522
Sarcoma	(000400)	IN 105-105	2	40	23	15	18			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1			
Pituitary	(000410)	IN 105-105	1	1	0	0	0	1.0000	0.8139	0.8555
Adenoma	(000100)	IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Preputial gland	(000420)	FA 88	1	1	0	0	0	1.0000	0.8171	0.8574
Carcinoma	(000140)	FA 88	2	69	36	28	35			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Salivary gland	(000480)	IN 105-105	1	0	1	0	0	0.5876	0.5876	0.6514
Fibroma (adeno-)	(000171)	IN 105-105	2	40	22	15	19			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	0	0			
Seminal vesicle	(000490)	IN 79-91	1	1	0	0	0	1.0000	0.9122	0.9298
Adenoma	(000100)	IN 79-91	2	15	6	13	8			
		IN 105-105	1	1	0	0	0			
		IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	0	0			
Skin	(000510)	IN 53-78	1	0	1	0	0	0.2795	0.2601	0.2715
Adenoma	(000100)	IN 53-78	2	17	5	9	6			
		IN 79-91	1	0	1	2	1			
		IN 79-91	2	16	5	11	7			
		IN 92-104	1	4	1	0	3			
		IN 92-104	2	22	11	8	10			
		IN 105-105	1	5	3	3	2			
		IN 105-105	2	35	20	12	17			
Spontaneous tumor pct: 9%		in ctrl. - Total	-	9	6	5	6			
Skin	(000510)	IN 105-105	1	1	0	0	0	1.0000	0.8139	0.8555
Carcinoma	(000140)	IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0			
Skin	(000510)	IN 92-104	1	1	0	1	0	0.6628	0.6531	0.6873
Lymphangioma	(000260)	IN 92-104	2	25	12	7	13			
		IN 105-105	1	0	1	0	0			
		IN 105-105	2	40	22	15	19			
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	1	0			

Table 10a (Continued)

Skin	(000510)	FA 73	1	0	1	0	0	0.5769	0.5912	0.6543
Sarcoma	(000400)	FA 73	2	88	41	37	41			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
Skin	(000510)	IN 105-105	1	0	0	0	1	0.1959	0.0366	0.0522
Sarcoma (carcino-L)	(000402)	IN 105-105	2	40	23	15	18			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	0	1			
Spinal cord	(000520)	IN 105-105	1	1	0	0	0	1.0000	0.8139	0.8555
Glioma	(000190)	IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Spleen	(000530)	IN 105-105	1	1	0	0	0	1.0000	0.8139	0.8555
Haemangioma	(000200)	IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Stomach	(000550)	IN 105-105	1	1	0	0	0	1.0000	0.8139	0.8555
Polyp	(000320)	IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Testicles	(000560)	IN 79-91	1	1	0	0	0	1.0000	0.9122	0.9298
Seminoma	(000430)	IN 79-91	2	15	6	13	8			
		IN 105-105	1	1	0	0	0			
		IN 105-105	2	39	23	15	19			
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	0	0	0			
Testicles	(000560)	IN 92-104	1	2	0	0	0	0.6373	0.6110	0.6369
Tumour (interstitial cell)	(001003)	IN 92-104	2	24	12	8	13			
		IN 105-105	1	1	1	1	1			
		IN 105-105	2	39	22	14	19			
Spontaneous tumor pct: 3% in ctrl.		- Total	-	3	1	1	1			
Thymus	(000590)	IN 92-104	1	0	0	1	0	0.3559	0.3398	0.4003
Lymphoma	(000270)	IN 92-104	2	26	12	7	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	0			
Thymus	(000590)	IN 79-91	1	0	0	0	1	0.1860	0.0419	0.0598
Thymoma	(000460)	IN 79-91	2	16	6	13	7			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	0	1			
Urinary bladder	(000630)	FA 82	1	0	0	1	0	0.3830	0.3387	0.4012
Sarcoma	(000400)	FA 82	2	78	38	33	38			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	0			
Localisation unknown	(001000)	IN 105-105	1	0	2	0	0	0.6349	0.6235	0.6678
Adenoma	(000100)	IN 105-105	2	40	21	15	19			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	2	0	0			
Multiple Organs	(001100)	IN 105-105	1	1	0	0	0	0.9380	0.9140	0.9224
Leukaemia	(000230)	IN 105-105	2	39	23	15	19			
		FA 51	1	0	0	0	1			
		FA 51	2	99	47	46	46			
		FA 70	1	1	0	0	0			
		FA 70	2	91	42	40	43			
		FA 84	1	1	0	0	0			
		FA 84	2	76	37	31	38			
		FA 86	1	1	0	0	0			
		FA 86	2	73	36	28	37			
		FA 89	1	0	0	1	0			
		FA 89	2	67	36	27	35			
		FA 99	1	1	0	0	0			
		FA 99	2	56	28	18	25			
		FA 103	1	2	0	0	0			
		FA 103	2	42	26	16	22			
Spontaneous tumor pct: 7% in ctrl.		- Total	-	7	0	1	1			
Multiple Organs	(001100)	IN 105-105	1	7	6	3	2	0.3630	0.3510	0.3596
Lymphoma	(000270)	IN 105-105	2	33	17	12	17			

Table 10a (Continued)

FA 10	1	0	1	0	0	
FA 10	2	100	49	50	51	
FA 49	1	0	0	1	0	
FA 49	2	99	47	46	47	
FA 58	1	0	0	1	0	
FA 58	2	99	47	44	44	
FA 61	1	0	1	0	0	
FA 61	2	96	45	41	44	
FA 67	1	1	1	0	0	
FA 67	2	94	43	40	43	
FA 73	1	1	0	0	0	
FA 73	2	87	42	37	41	
FA 77	1	1	0	0	0	
FA 77	2	84	41	37	41	
FA 79	1	1	0	0	0	
FA 79	2	81	41	36	40	
FA 80	1	1	0	0	0	
FA 80	2	80	40	35	39	
FA 82	1	0	0	1	0	
FA 82	2	78	38	33	38	
FA 84	1	1	0	0	0	
FA 84	2	76	37	31	38	
FA 86	1	2	0	0	1	
FA 86	2	72	36	28	36	
FA 87	1	0	0	0	1	
FA 87	2	70	36	28	35	
FA 89	1	0	0	0	1	
FA 89	2	67	36	28	34	
FA 92	1	2	0	0	0	
FA 92	2	64	35	23	32	
FA 93	1	0	0	0	1	
FA 93	2	62	35	22	31	
FA 95	1	0	0	0	2	
FA 95	2	62	32	18	29	
FA 96	1	0	0	0	1	
FA 96	2	60	31	18	28	
FA 97	1	1	0	0	0	
FA 97	2	58	31	18	28	
FA 98	1	1	1	0	1	
FA 98	2	57	29	18	26	
FA 99	1	0	1	0	1	
FA 99	2	57	27	18	24	
FA 100	1	1	1	0	0	
FA 100	2	54	26	18	24	
FA 101	1	1	0	1	0	
FA 101	2	49	26	17	22	
FA 102	1	2	0	0	0	
FA 102	2	45	26	16	22	
FA 103	1	0	1	0	1	
FA 103	2	44	25	16	21	
FA 104	1	0	0	0	1	
FA 104	2	42	25	15	19	
Spontaneous tumor pct: 23%	in ctrl. - Total	-	23	13	7	13

APPEARS THIS WAY
ON ORIGINAL

Table 10b

Analysis of Carcinogenic Potential in Female Mouse
Test of Dose-Response (Tumor) Positive Linear Trend

Dose Levels Included: CTRL LOW MED HIGH (0 2 4 8)
Missing value in Tumor-Caused Death is treated as tumor not causing death
Tumor Type: IN: Incidental (nonfatal) tumor, FA: Fatal tumor.

ORGAN/TISSUE NAME AND TUMOR NAME	(ORG#) (TMR#)	TUMOR TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY TABLE	EXACT PROB	ASYMP TOTIC	ASYMP (CONTI NUITY CORR)			
Adrenals	(000100)	IN 79-91	1	0 1 0 0	0.8331	0.7934	0.8253			
Adenoma	(000100)	IN 79-91	2	26 14 13 12						
		IN 100-100	1	1 0 0 0						
		IN 100-100	2	24 12 9 13						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 1 0 0					
Adrenals	(000100)	IN 0-52	1	0 1 0 0	0.4375	0.4622	0.5378			
Lipoma	(000240)	IN 0-52	2	9 3 1 2						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-				0 1 0 0		
Adrenals	(000100)	IN 92-99	1	0 1 0 0	0.4339	0.4167	0.4654			
Lymphoma	(000270)	IN 92-99	2	15 7 8 5						
		FA 98	1	0 0 1 0						
		FA 98	2	30 14 12 14						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 1 0					
Anus	(000110)	FA 93	1	0 1 0 0	0.5889	0.5678	0.6533			
Histiocytoma	(000210)	FA 93	2	37 18 18 16						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 0 0					
Anus	(000110)	IN 100-100	1	1 0 0 0	1.0000	0.8148	0.8547			
Sarcoma	(000400)	IN 100-100	2	24 12 9 13						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0					
Brain	(000130)	IN 79-91	1	0 1 0 0	0.6061	0.5949	0.6600			
Ependymoma	(000160)	IN 79-91	2	26 14 13 12						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-				0 1 0 0		
Harder's gland	(000190)	IN 100-100	1	1 1 0 0	0.8247	0.7934	0.8246			
Adenoma	(000100)	IN 100-100	2	24 11 9 13						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 1 0 0					
Intestine (large)	(000220)	IN 79-91	1	1 0 0 0	1.0000	0.8236	0.8647			
Polyp	(000320)	IN 79-91	2	25 15 13 12						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1 0 0 0					
Liver	(000280)	IN 100-100	1	0 1 0 3	0.0148	0.0069	0.0087			
Adenoma (hepatocellular)	(000103)	IN 100-100	2	25 11 9 10						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 0 3		(P<0.025)			
Liver	(000280)	IN 100-100	1	0 1 0 0	0.5763	0.5992	0.6500			
Carcinoma (hepatocellular)	(000142)	IN 100-100	2	25 11 9 13						
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0 1 0 0					
Liver	(000280)	IN 53-78	1	0 0 1 0	0.5338	0.5023	0.5324			
Haemangioma	(000200)	IN 53-78	2	25 11 17 17						
		IN 79-91	1	1 0 0 0						
		IN 79-91	2	25 14 13 12						
		FA 85	1	0 1 0 0						
		FA 85	2	52 26 26 23						
		FA 92	1	1 0 0 0						
		FA 92	2	39 20 18 18						
		FA 95	1	0 0 0 1						
		FA 95	2	34 17 18 15						
Spontaneous tumor pct: 2% in ctrl. - Total				-				2 1 1 1		

Table 10b (Continued)

Liver	(000280)	FA 88	1	0	0	1	0	0.3717	0.3072	0.3706
Leukaemia	(000230)	FA 88	2	49	22	22	19			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
Lungs	(000290)	IN 53-78	1	3	0	1	0	0.9171	0.9034	0.9091
Adenoma	(000100)	IN 53-78	2	21	11	17	17			
		IN 79-91	1	1	2	2	1			
		IN 79-91	2	24	13	11	11			
		IN 92-99	1	0	1	1	0			
		IN 92-99	2	14	5	8	5			
		IN 100-100	1	4	2	2	1			
		IN 100-100	2	21	10	7	12			
		FA 75	1	1	0	0	0			
		FA 75	2	72	38	34	33			
		FA 90	1	1	0	0	0			
		FA 90	2	44	22	20	18			
		FA 92	1	0	1	0	0			
		FA 92	2	40	19	18	18			
		FA 95	1	0	1	0	0			
		FA 95	2	34	16	18	16			
		FA 98	1	1	0	0	0			
		FA 98	2	29	14	13	14			
Spontaneous tumor pct: 11% in ctrl. - Total			-	11	7	6	2			
Lungs	(000290)	IN 79-91	1	0	1	0	0	0.5649	0.5062	0.5453
Carcinoma	(000140)	IN 79-91	2	26	14	13	12			
		FA 78	1	0	1	0	0			
		FA 78	2	68	36	32	31			
		FA 98	1	0	0	1	0			
		FA 98	2	30	14	12	14			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	2	1	0			
Lungs	(000290)	IN 100-100	1	1	0	0	0	1.0000	0.8148	0.8547
Carcinoma (adeno-)	(000141)	IN 100-100	2	24	12	0	13			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
Lymph node (mesenteric)	(000302)	IN 53-78	1	1	0	0	0	0.7975	0.7712	0.7883
Lymphoma	(000270)	IN 53-78	2	24	11	18	16			
		IN 79-91	1	1	0	0	0			
		IN 79-91	2	25	15	13	12			
		IN 92-99	1	2	0	1	0			
		IN 92-99	2	13	8	8	5			
		IN 100-100	1	1	1	1	0			
		IN 100-100	2	24	11	8	13			
		FA 59	1	0	0	0	1			
		FA 59	2	89	44	44	42			
Spontaneous tumor pct: 5% in ctrl. - Total			-	5	1	2	1			
Ovaries	(000370)	IN 53-78	1	1	0	0	0	1.0000	0.8533	0.8274
Adenoma (cyst-)	(000101)	IN 53-78	2	24	11	18	17			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
Ovaries	(000370)	IN 53-78	1	1	0	0	0	0.2027	0.1868	0.1946
Tumour (granulosa cell-)	(001002)	IN 53-78	2	23	11	17	17			
		IN 79-91	1	2	1	3	1			
		IN 79-91	2	23	14	10	10			
		IN 92-99	1	6	2	2	3			
		IN 92-99	2	9	6	7	2			
		IN 100-100	1	11	9	5	8			
		IN 100-100	2	14	3	4	5			
		FA 73	1	0	0	1	0			
		FA 73	2	74	40	34	34			
		FA 77	1	1	0	0	0			
		FA 77	2	69	38	33	31			
		FA 79	1	0	0	0	1			
		FA 79	2	66	35	31	29			
		FA 81	1	1	0	0	0			
		FA 81	2	61	32	29	27			
Spontaneous tumor pct: 22% in ctrl. - Total			-	22	12	11	13			

Table 10b (Continued)

Pancreas	(000380)	IN 79-91	1	0	0	1	0	0.3716	0.2613	0.3022
Carcinoma	(000140)	IN 79-91	2	26	15	12	12			
		FA 97	1	0	0	1	0			
		FA 97	2	33	14	16	14			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	2	0			
Pancreas	(000380)	IN 79-91	1	0	1	0	0	0.6061	0.5949	0.6600
Insuloma	(000220)	IN 79-91	2	26	14	13	12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
Parathyroids	(000390)	IN 100-100	1	2	4	0	0	0.9112	0.8838	0.8967
Adenoma	(000100)	IN 100-100	2	23	8	9	13			
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	4	0	0			
Pituitary	(000410)	IN 53-78	1	0	1	0	0	0.4450	0.4240	0.4373
Adenoma	(000100)	IN 53-78	2	25	10	18	17			
		IN 79-91	1	0	2	1	2			
		IN 79-91	2	26	12	12	10			
		IN 92-99	1	1	3	0	0			
		IN 92-99	2	13	5	9	5			
		IN 100-100	1	7	5	3	4			
		IN 100-100	2	18	7	6	9			
		FA 91	1	0	1	0	0			
		FA 91	2	43	20	19	18			
		FA 95	1	1	0	0	0			
		FA 95	2	33	17	18	16			
Spontaneous tumor pct: 9% in ctrl.		- Total	-	9	12	4	6			
Skin	(000510)	IN 79-91	1	1	0	0	0	1.0000	0.8236	0.8647
Adenocarcinoid	(000090)	IN 79-91	2	25	15	13	12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Skin	(000510)	IN 92-99	1	2	0	0	0	1.0000	0.9077	0.9279
Adenoma	(000100)	IN 92-99	2	13	8	9	5			
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	0	0	0			
Skin	(000510)	IN 92-99	1	0	1	0	0	0.4267	0.3961	0.4192
Carcinoma	(000140)	IN 92-99	2	15	7	8	5			
		IN 100-100	1	2	0	0	1			
		IN 100-100	2	23	12	9	12			
		FA 65	1	1	0	0	0			
		FA 65	2	84	42	40	41			
		FA 72	1	0	0	0	1			
		FA 72	2	75	41	36	36			
		FA 84	1	0	1	0	0			
		FA 84	2	52	29	27	26			
		FA 98	1	0	0	1	0			
		FA 98	2	30	14	12	14			
Spontaneous tumor pct: 3% in ctrl.		- Total	-	3	2	1	2			
Skin	(000510)	IN 92-99	1	0	0	1	0	0.3784	0.2867	0.3530
Carcinoma (squamous cell)	(000143)	IN 92-99	2	15	8	8	5			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	0			
Skin	(000510)	IN 92-99	1	1	0	0	0	1.0000	0.8226	0.8668
Haemangioma	(000200)	IN 92-99	2	14	8	9	5			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
Skin	(000510)	IN 92-99	1	0	0	1	0	0.3784	0.2867	0.3530
Lymphangioma	(000260)	IN 92-99	2	15	8	8	5			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	0			
Skin	(000510)	IN 100-100	1	1	0	0	0	1.0000	0.8148	0.8547
Myoma	(000280)	IN 100-100	2	24	12	9	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			

Table 10b (Continued)

Skin	(000510)	IN 92-99	1	1	0	0	0
Papilloma	(000300)	IN 92-99	2	14	8	9	5
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0
Skin	(000510)	IN 100-100	1	1	2	0	0
Sarcoma	(000400)	IN 100-100	2	24	10	9	13
	FA 81		1	1	0	0	0
	FA 81		2	61	32	29	27
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	2	0	0
Skin	(000510)	IN 100-100	1	0	0	0	1
Sarcoma (angio-)	(000401)	IN 100-100	2	25	12	9	12
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	0	1
Skin	(000510)	IN 100-100	1	1	0	0	0
Sarcoma (leiomyo-)	(000404)	IN 100-100	2	24	12	9	13
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0
Spleen	(000530)	IN 79-91	1	0	1	0	0
Leukaemia	(000230)	IN 79-91	2	26	14	13	12
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0
Stomach	(000550)	FA 98	1	1	0	0	0
Carcinoma (squamous cell)	(000143)	FA 98	2	29	14	13	14
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0
Stomach	(000550)	IN 100-100	1	0	0	1	0
Lymphoma	(000270)	IN 100-100	2	25	12	8	13
	FA 98		1	0	0	0	1
	FA 98		2	30	14	13	13
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	1
Stomach	(000550)	IN 100-100	1	0	0	1	0
Papilloma	(000300)	IN 100-100	2	25	12	8	13
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	1	0
Stomach	(000550)	IN 79-91	1	0	0	0	1
Polyp	(000320)	IN 79-91	2	26	15	13	11
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	0	1
Thymus	(000590)	IN 53-78	1	0	1	0	0
Lymphoma	(000270)	IN 53-78	2	25	10	18	17
	IN 100-100		1	1	0	0	0
	IN 100-100		2	24	12	9	13
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	1	0	0
Thymus	(000590)	FA 70	1	1	0	0	0
Sarcoma	(000400)	FA 70	2	76	41	37	40
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0
Thyroids	(000610)	IN 53-78	1	1	0	0	0
Adenoma	(000100)	IN 53-78	2	24	11	18	17
	IN 100-100		1	1	0	0	0
	IN 100-100		2	24	12	9	13
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	0	0	0
Uterus	(000650)	FA 97	1	0	0	1	0
Carcinoma	(000140)	FA 97	2	33	14	16	14
	FA 98		1	0	0	1	0
	FA 98		2	30	14	12	14
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	0	2	0
Uterus	(000650)	IN 100-100	1	0	1	0	0
Fibroma (adeno-)	(000171)	IN 100-100	2	25	11	9	13
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0

Table 10b (Continued)

Uterus	(000650)	IN 79-91	1	0	0	0	1	
Myoma	(000280)	IN 79-91	2	26	15	13	11	0.1112 0.0624 0.0781
		IN 100-100	1	0	0	1	0	
		IN 100-100	2	25	12	8	13	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	1	1	
Uterus	(000650)	IN 100-100	1	0	0	0	1	0.1500 0.1240 0.1352
Sarcoma	(000400)	IN 100-100	2	25	12	9	12	
		FA 50	1	1	0	0	0	
		FA 50	2	92	46	49	47	
		FA 56	1	0	0	0	1	
		FA 56	2	90	46	48	46	
		FA 87	1	0	0	1	0	
		FA 87	2	50	23	24	21	
		FA 91	1	1	0	0	0	
		FA 91	2	42	21	19	18	
		FA 92	1	0	0	0	1	
		FA 92	2	40	20	18	17	
		FA 93	1	0	1	0	0	
		FA 93	2	37	18	18	16	
		FA 95	1	0	1	0	0	
		FA 95	2	34	16	18	16	
		FA 97	1	0	0	1	0	
		FA 97	2	33	14	16	14	
		FA 99	1	0	1	0	0	
		FA 99	2	26	13	10	13	
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	3	2	3	
Uterus	(000650)	FA 81	1	1	0	0	0	1.0000 0.8174 0.8503
Sarcoma (angio-)	(000401)	FA 81	2	61	32	29	27	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0	
Uterus	(000650)	IN 100-100	1	1	0	0	0	0.8305 0.7956 0.8272
Sarcoma (leiomyo-)	(000404)	IN 100-100	2	24	12	9	13	
		FA 95	1	0	1	0	0	
		FA 95	2	34	16	18	16	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	1	0	0	
Uterine region	(000651)	IN 79-91	1	0	0	0	1	0.1818 0.0338 0.0490
Haemangioma	(000200)	IN 79-91	2	26	15	13	11	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	0	1	
Localisation unknown	(001000)	IN 100-100	1	1	0	0	0	1.0000 0.8148 0.8547
Carcinoma	(000140)	IN 100-100	2	24	12	9	13	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0	
Localisation unknown	(001000)	IN 79-91	1	1	0	0	0	1.0000 0.8236 0.8647
Sarcoma	(000400)	IN 79-91	2	25	15	13	12	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0	
Multiple Organs	(001100)	IN 100-100	1	2	1	0	0	0.7457 0.7270 0.7400
Leukaemia	(000230)	IN 100-100	2	23	11	9	13	
		FA 28	1	1	0	0	0	
		FA 28	2	99	49	50	49	
		FA 45	1	1	0	0	0	
		FA 45	2	94	48	49	47	
		FA 50	1	1	0	0	0	
		FA 50	2	92	46	49	47	
		FA 56	1	0	0	1	1	
		FA 56	2	90	46	47	46	
		FA 58	1	0	1	0	0	
		FA 58	2	90	45	44	44	
		FA 70	1	0	0	0	1	
		FA 70	2	77	41	37	39	
		FA 72	1	1	0	0	0	
		FA 72	2	74	41	36	37	
		FA 74	1	0	1	0	0	
		FA 74	2	74	39	34	33	

Table 10b (Continued)

FA 76	1	0	0	1	0	
FA 76	2	70	38	33	33	
FA 77	1	1	0	0	0	
FA 77	2	69	38	33	31	
FA 84	1	0	1	0	0	
FA 84	2	52	29	27	26	
FA 85	1	0	1	0	0	
FA 85	2	52	26	26	23	
FA 92	1	0	0	0	1	
FA 92	2	40	20	18	17	
FA 97	1	1	0	0	0	
FA 97	2	32	14	17	14	
Spontaneous tumor pct: 8%	in ctrl. - Total	-	8	5	2	3
Multiple Organs	(001100) IN 79-91	1	0	0	1	0
Lymphoma	(000270) IN 79-91	2	10	12	5	5
	IN 92-99	1	1	1	2	0
	IN 92-99	2	7	4	5	4
	IN 100-100	1	12	9	1	8
	IN 100-100	2	13	3	8	5
	FA 58	1	1	1	0	0
	FA 58	2	89	45	44	44
	FA 59	1	2	0	0	0
	FA 59	2	87	44	44	43
	FA 61	1	0	0	2	0
	FA 61	2	86	44	41	42
	FA 62	1	0	0	0	1
	FA 62	2	86	44	40	41
	FA 66	1	0	1	0	0
	FA 66	2	84	41	40	41
	FA 67	1	1	0	1	0
	FA 67	2	83	41	39	40
	FA 68	1	1	0	0	0
	FA 68	2	82	41	39	40
	FA 69	1	2	0	1	0
	FA 69	2	79	41	37	40
	FA 70	1	1	0	1	0
	FA 70	2	76	41	36	40
	FA 72	1	0	0	1	2
	FA 72	2	75	41	35	35
	FA 74	1	1	1	0	0
	FA 74	2	73	39	34	33
	FA 75	1	2	0	0	0
	FA 75	2	71	38	34	33
	FA 76	1	0	0	0	1
	FA 76	2	70	38	34	32
	FA 77	1	0	0	1	0
	FA 77	2	70	38	32	31
	FA 78	1	2	0	0	0
	FA 78	2	66	37	32	31
	FA 79	1	2	0	0	0
	FA 79	2	64	35	31	30
	FA 80	1	2	0	1	0
	FA 80	2	62	34	29	28
	FA 81	1	3	0	1	1
	FA 81	2	59	32	28	26
	FA 83	1	2	0	0	0
	FA 83	2	54	30	27	26
	FA 84	1	0	0	1	2
	FA 84	2	52	30	26	24
	FA 85	1	0	1	0	0
	FA 85	2	52	26	26	23
	FA 86	1	2	0	1	1
	FA 86	2	50	24	25	21
	FA 87	1	1	1	1	2
	FA 87	2	49	22	24	19
	FA 88	1	2	0	2	0
	FA 88	2	47	22	21	19

0.7218 0.7125 0.7185

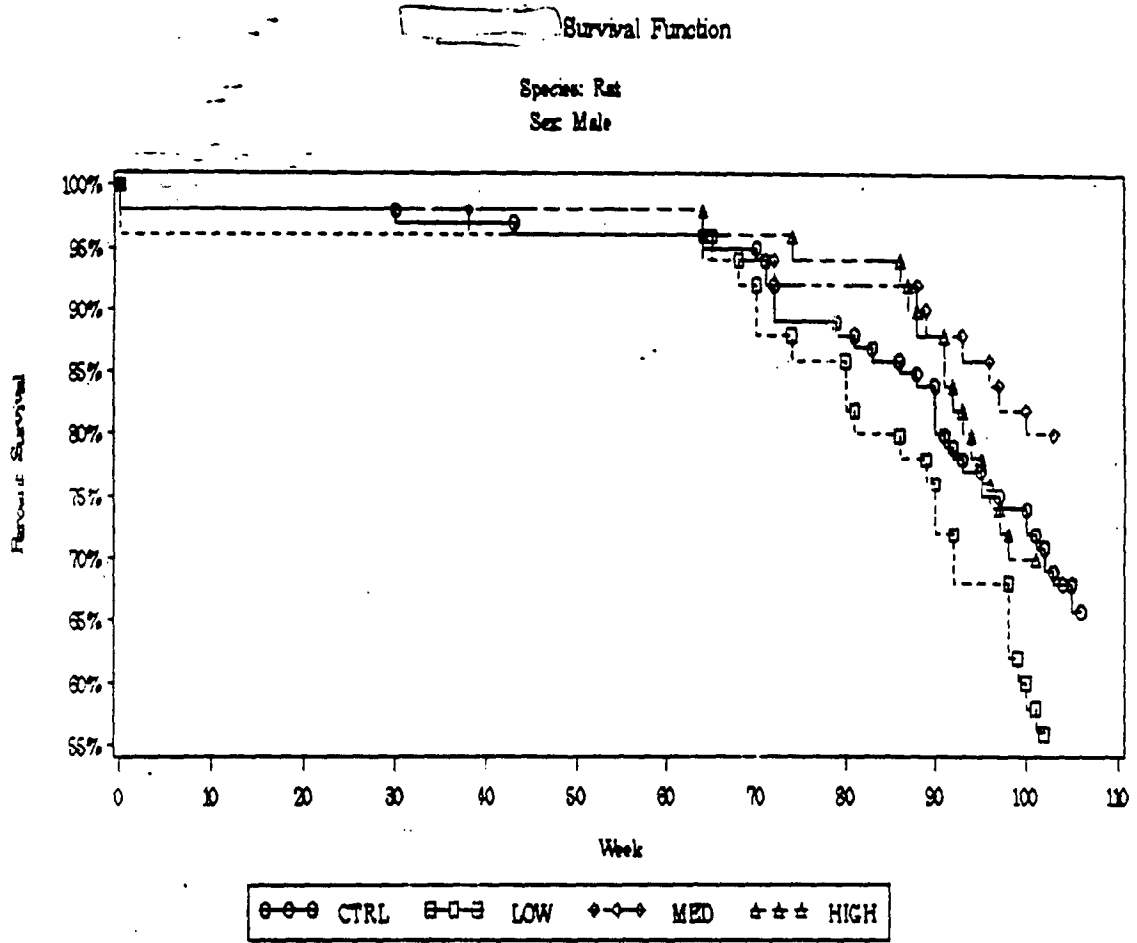
Table 10b (Continued)

FA 89	1	1	0	0	1	
FA 89	2	46	22	21	18	
FA 90	1	1	1	0	0	
FA 90	2	44	21	20	18	
FA 92	1	1	1	0	0	
FA 92	2	39	19	18	18	
FA 93	1	1	0	0	0	
FA 93	2	36	19	18	16	
FA 94	1	1	0	0	0	
FA 94	2	35	17	18	16	
FA 95	1	0	1	0	1	
FA 95	2	34	16	18	15	
FA 96	1	0	0	1	0	
FA 96	2	33	15	17	14	
FA 97	1	2	0	0	0	
FA 97	2	31	14	17	14	
FA 98	1	2	0	0	0	
FA 98	2	28	14	13	14	
FA 99	1	0	1	1	0	
FA 99	2	26	13	9	13	
Spontaneous tumor pct: 49%	in ctrl. - Total	-	49	19	20	20

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Figure 1a



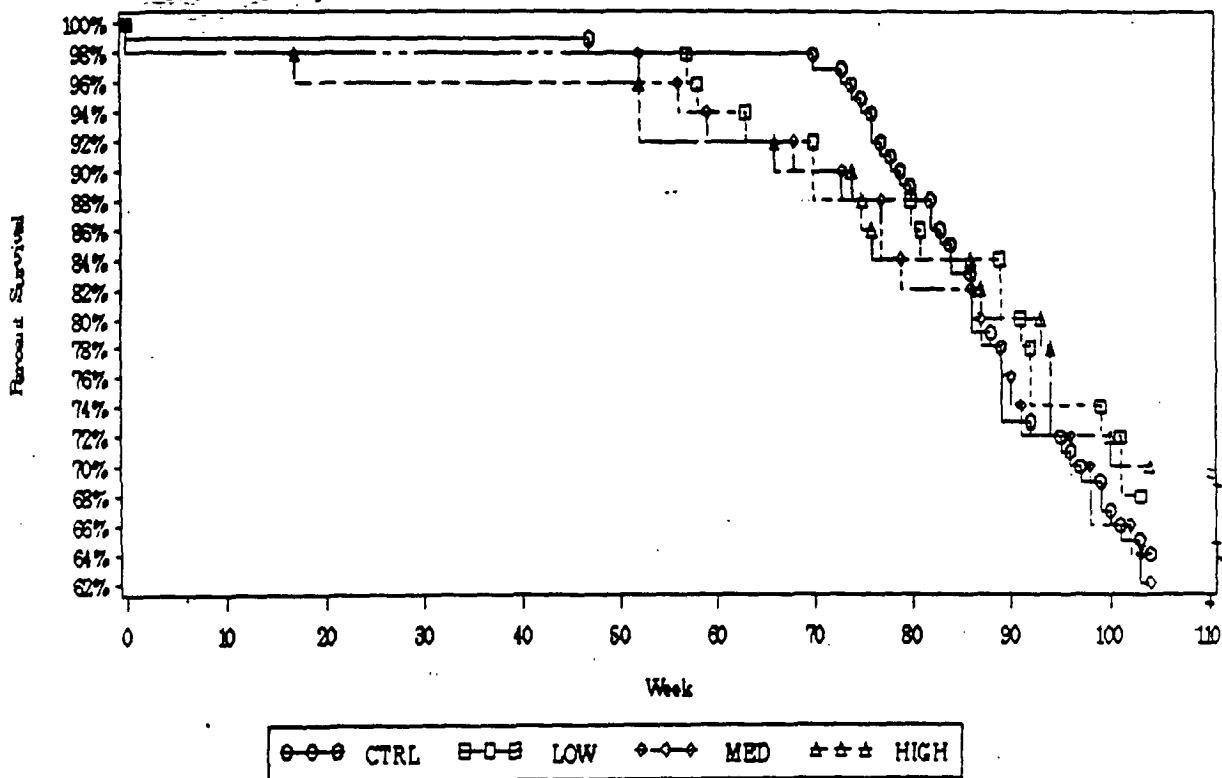
APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Figure 1b

Kaplan-Meier Survival Function

Species: Rat
Sex: Female



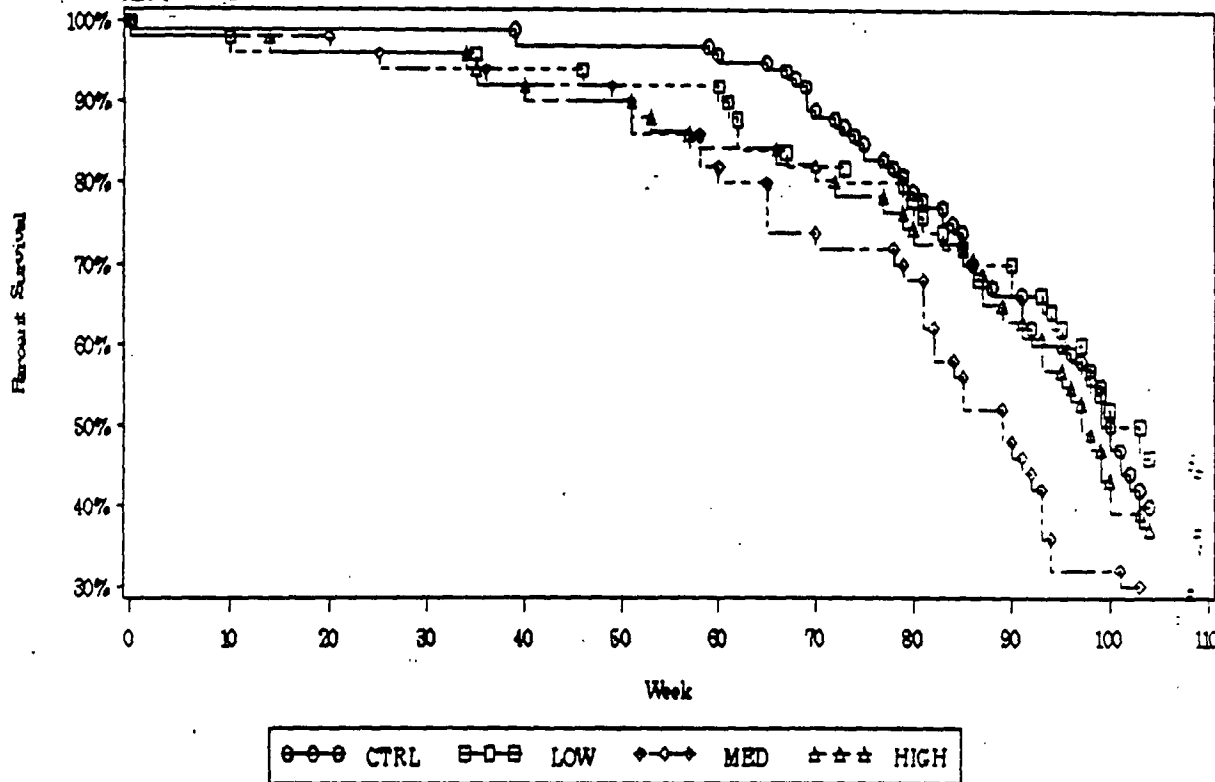
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Figure 2a

Kaplan-Meier Survival Function

Species: Mouse
Sex: Male



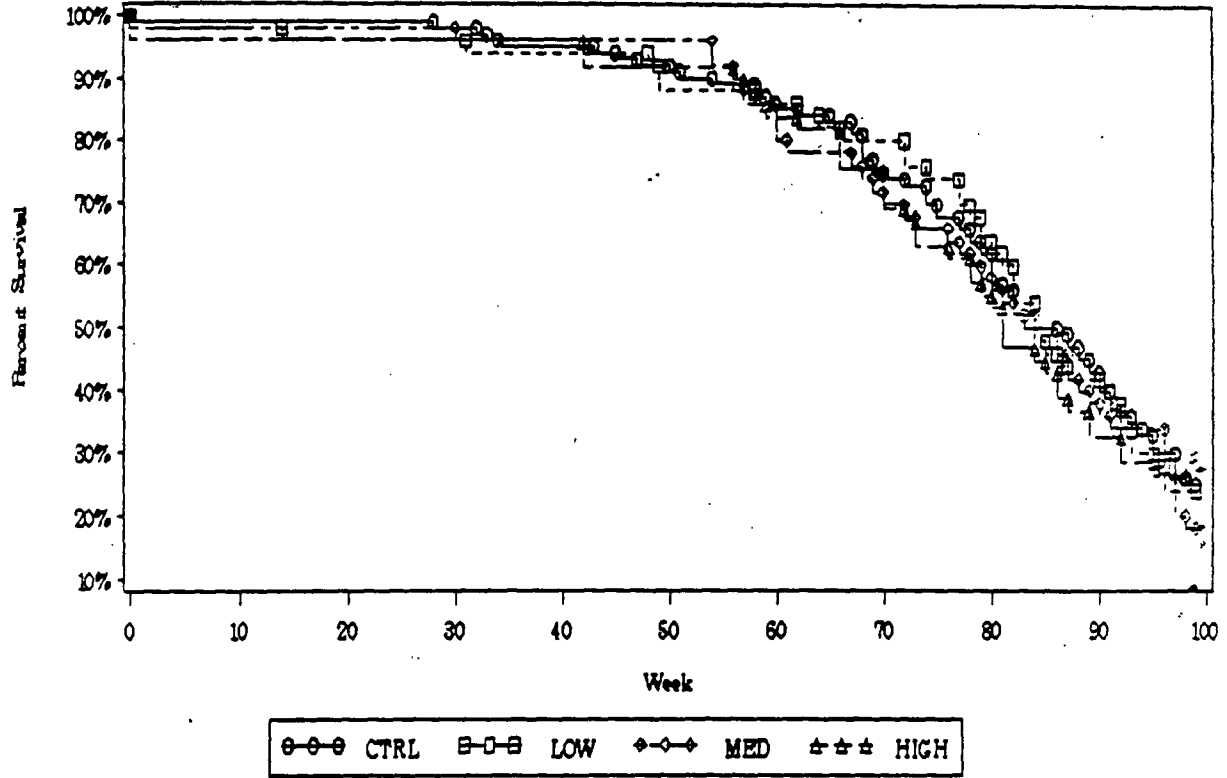
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APPEARS THIS WAY
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Figure 2b

Kaplan-Meier Survival Function

Species: Mouse
Sex: Female



APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

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