

Appendix

Rat Study

Analyses of Mortality

Number of animals died at different time-intervals, male
 Number of animals died at different time-intervals, female
 Intercurrent mortality data for the male and female rats, male
 Intercurrent mortality data for the male and female rats, female
 p-value of the test of homogeneity and positive linear trends, male
 p-value of the test of homogeneity and positive linear trends, female

Table number

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Analyses of Tumor Incidence

Male
 Female
 Female – excluding High dosed group

Table 7
 Table 8a
 Table 8b

Mice Study

Analyses of Mortality

Number of animals died at different time-intervals, male
 Number of animals died at different time-intervals, female
 Intercurrent mortality data for the male and female rats, male
 Intercurrent mortality data for the male and female rats, female
 p-value of the test of homogeneity and positive linear trends, male
 p-value of the test of homogeneity and positive linear trends, female

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Analyses of Tumor Incidence without combination

Male
 Female

Table 15
 Table 16

Combined Analyses

Analyses of Tumor Incidence without combination

Rat / Male
 Rat / Female
 Rat / Female – excluding High Dose Group
 Mice / Male
 Mice / Female

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Table 1

Number of Animals
Species: Rat
Sex: Male

	Treatment Group				
	CTRL	LOW	MED	HIGH	Total
	N	N	N	N	N
Week					
0-50	11	16	30	38	95
51-80	26	32	37	37	132
81-104	45	40	38	26	149
105-105	26	32	14	12	84
Total	108	120	119	113	460

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Table 2

Number of Animals
Species: Rat
Sex: Female

	Treatment Group				
	CTRL	LOW	MED	HIGH	Total
Week	N	N	N	N	N
0-50	2	4	33	66	105
51-80	31	36	30	19	116
81-104	47	51	29	13	140
105-105	19	32	19	.	70
INTERIM	10	.	.	12	22
Total	109	123	111	110	453

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Table 3

Analysis of Mortality
Species: Rat
Sex: Male

week	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
0-50	11	108	10.2	16	120	13.3	30	119	25.2	38	113	33.6
51-80	26	97	34.3	32	104	40.0	37	89	56.3	37	75	66.4
81-104	45	71	75.9	40	72	73.3	38	52	88.2	26	38	89.4
105- 105	26	108	24.1	32	120	26.7	14	119	11.8	12	113	10.6

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Table 4

Analysis of Mortality
Species: Rat
Sex: Female

week	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
0-50	2	109	1.8	4	123	3.3	33	111	29.7	66	110	60.0
51-80	31	107	30.3	36	119	32.5	30	78	56.8	19	44	77.3
81-104	47	76	73.4	51	83	74.0	29	48	82.9	13	25	89.1
105- 105	19	29	90.8	32	123	26.0	19	111	17.1	.	.	.
INTER- IM	10	109	9.2	.	.	.	.	.	.	12	110	10.9

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Table 5

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	31.27	0.0000
	Depart from Trend	3.71	0.1561
	Homogeneity	34.99	0.0000
Kruskal-wallis	Dose-Mortality Trend	39.33	0.0000
	Depart from Trend	2.70	0.2594
	Homogeneity	42.02	0.0000

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Table 6

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	95.08	0.0000
	Depart from Trend	99.21	0.0000
	Homogeneity	194.29	0.0000
kruskal-wallis	Dose-Mortality Trend	138.86	0.0000
	Depart from Trend	74.38	0.0000
	Homogeneity	213.24	0.0000

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Table 7

Analysis of Carcinogenic Potential in Male Rat
 Test of Dose-Response (Tumor) Positive Linear Trend
 Dose Levels Included: CTRL LOW MED HIGH (0, 2.5, 5, 7.5)

Study No. 97095
 Run Date & Time: June 28, 2001 (16:55)
 Source: C:\N21-341\RAT\MALE\XAnimalX.txt

Note: Dose Levels Included: CTRL LOW MED HIGH (0 2.5 5 7.5)
 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 TABLES	EXACT ASYMP PROB	ASYMP /CONT CORR	PROB =P(STAT .GE. OBSERVED)
BRAIN	(1510)	IN 81-104	1	0 0 0 1	0.079	0.056	0.063
Astrocytoma, Malignant	(1)	IN 81-104	2	45 39 35 25			
		FA 62	1	0 0 0 1			
		FA 62	2	90 98 76 60			
		FA 78	1	0 0 1 0			
		FA 78	2	76 77 54 42			
		FA 80	1	0 1 0 0			
		FA 80	2	72 73 54 41			
		FA 83	1	0 1 0 0			
		FA 83	2	67 66 48 35			
		FA 84	1	0 0 1 0			
		FA 84	2	65 66 47 34			
		FA 99	1	0 0 1 0			
		FA 99	2	44 43 31 15			
		FA 100	1	0 0 1 0			
		FA 100	2	40 42 26 14			
		FA 105	1	1 0 0 0			
		FA 105	2	25 32 14 12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1 2 4 2			
BRAIN	(1510)	IN 51-80	1	0 0 1 0	0.372	0.305	0.332
Granular Cell Tumor, Beni	(2)	IN 51-80	2	26 31 36 37			
		IN 81-104	1	0 0 1 0			
		IN 81-104	2	44 40 37 26			
		IN 105-105	1	0 1 0 1			
		IN 105-105	2	26 31 14 11			
		FA 66	1	0 1 0 0			
		FA 66	2	88 95 73 57			
		FA 97	1	1 0 0 0			
		FA 97	2	47 44 33 17			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1 2 2 1			
BRAIN	(1510)	FA 102	1	0 0 1 0	0.307	0.177	0.234
Meningioma, Malignant	(3)	FA 102	2	36 36 19 12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 0 1 0			
BRAIN	(1510)	IN 105-105	1	0 0 1 0	0.309	0.198	0.258
Meningioma, Benign	(4)	IN 105-105	2	26 32 13 12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 0 1 0			
BRAIN	(1510)	IN 0-50	1	0 0 0 1	0.400	0.162	0.215
Malignant Reticulosis	(5)	IN 0-50	2	11 16 30 37			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 0 0 1			
SPINAL CORD, LUMBAR	(1520)	IN 0-50	1	0 0 0 1	0.397	0.162	0.215
Malignant Reticulosis	(103)	IN 0-50	2	11 15 30 36			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 0 0 1			
HEART	(1540)	FA 86	1	1 0 0 0	1.000	0.876	0.910
Atrio caval Mesothelioma,	(6)	FA 86	2	61 60 43 32			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1 0 0 0			
HEART	(1540)	IN 105-105	1	0 1 1 0	0.421	0.308	0.359
Hemangioma	(7)	IN 105-105	2	26 31 13 12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 1 0			
HEART	(1540)	IN 81-104	1	0 1 0 0	0.698	0.610	0.679
Endocardial Schwannoma, B	(8)	IN 81-104	2	45 39 38 26			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 0 0			
HEART	(1540)	FA 104	1	1 0 0 0	1.000	0.860	0.899
Endocardial Schwannoma, M	(9)	FA 104	2	29 32 15 12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1 0 0 0			
THYMUS	(1550)	IN 105-105	1	0 1 0 0	0.687	0.554	0.631
Thymoma, Benign	(10)	IN 105-105	2	25 29 14 11			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 0 0			
THYMUS	(1550)	IN 105-105	1	1 0 0 0	1.000	0.870	0.907
Thymoma, Malignant	(11)	IN 105-105	2	24 30 14 11			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1 0 0 0			
LUNG	(1570)	IN 51-80	1	0 1 0 1	0.322	0.225	0.259
Bronchiolar/Alveolar Aden	(12)	IN 51-80	2	26 31 37 36			
		IN 81-104	1	0 0 1 0			
		IN 81-104	2	45 40 37 26			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 1 1			
LUNG	(1570)	FA 99	1	0 1 0 0	0.671	0.553	0.631
Sarcoma, NOS	(13)	FA 99	2	44 42 32 15			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 0 0			
LIVER	(1580)	IN 51-80	1	0 0 0 1	0.275	0.214	0.237
Hepatocellular Carcinoma	(14)	IN 51-80	2	26 32 37 36			
		IN 81-104	1	1 1 1 0			

		IN 81-104	2	44	38	37	26	
		IN 105-105	1	0	0	0	1	
		IN 105-105	2	26	32	14	11	
		FA 89	1	0	1	0	0	
		FA 89	2	55	52	42	28	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	2	1	2	
LIVER	(1580)	IN 51-80	1	1	0	0	0	0.976 0.963 0.967
Hepatocellular Adenoma	(15)	IN 51-80	2	25	32	37	37	
		IN 81-104	1	5	2	1	0	
		IN 81-104	2	40	38	37	26	
		IN 105-105	1	1	0	1	1	
		IN 105-105	2	25	32	13	11	
Spontaneous tumor pct: 6% in ctrl.	-	Total	-	7	2	2	1	
SPLEEN	(1590)	IN 105-105	1	0	1	0	0	0.690 0.556 0.632
Hemangiosarcoma	(16)	IN 105-105	2	26	31	14	12	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0	
SPLEEN	(1590)	IN 105-105	1	1	0	0	0	0.891 0.802 0.838
Sarcoma, NOS	(17)	IN 105-105	2	25	32	14	12	
		FA 103	1	0	1	0	0	
		FA 103	2	33	32	16	12	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	1	0	0	
ADRENAL	(1600)	IN 51-80	1	3	0	0	0	0.995 0.993 0.994
Pheochromocytoma, Benign	(18)	IN 51-80	2	23	32	37	37	
		IN 81-104	1	12	8	8	2	
		IN 81-104	2	33	32	30	24	
		IN 105-105	1	10	8	4	3	
		IN 105-105	2	16	24	10	9	
Spontaneous tumor pct: 23% in ctrl.	-	Total	-	25	16	12	5	
ADRENAL	(1600)	IN 81-104	1	1	0	0	1	0.736 0.653 0.693
Pheochromocytoma, Maligna	(19)	IN 81-104	2	43	40	38	25	
		FA 104	1	1	0	0	0	
		FA 104	2	29	32	15	12	
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	0	0	1	
ADRENAL	(1600)	IN 51-80	1	0	1	0	0	0.939 0.885 0.909
Cortex, Adenoma	(20)	IN 51-80	2	26	31	37	37	
		IN 105-105	1	1	0	0	0	
		IN 105-105	2	25	32	14	12	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	1	0	0	
PITUITARY	(1610)	IN 0-50	1	1	0	1	0	0.964 0.960 0.961
Pars Distalis, Adenoma	(22)	IN 0-50	2	10	16	29	37	
		IN 51-80	1	7	10	14	6	
		IN 51-80	2	15	21	20	28	
		IN 81-104	1	17	22	18	14	
		IN 81-104	2	13	15	18	11	
		IN 105-105	1	13	20	9	7	
		IN 105-105	2	13	12	5	5	
		FA 53	1	0	0	1	0	
		FA 53	2	96	104	86	73	
		FA 62	1	0	0	0	1	
		FA 62	2	90	98	76	60	
		FA 66	1	1	0	0	0	
		FA 66	2	87	96	73	57	
		FA 69	1	0	0	1	0	
		FA 69	2	86	90	67	52	
		FA 71	1	0	0	1	1	
		FA 71	2	84	85	63	49	
		FA 74	1	3	0	0	0	
		FA 74	2	80	81	60	47	
		FA 77	1	0	1	0	0	
		FA 77	2	77	77	56	44	
		FA 79	1	0	0	0	1	
		FA 79	2	74	77	54	41	
		FA 81	1	0	1	0	0	
		FA 81	2	71	71	52	38	
		FA 82	1	1	0	0	1	
		FA 82	2	69	68	49	35	
		FA 83	1	1	0	0	0	
		FA 83	2	66	67	48	35	
		FA 84	1	0	1	0	0	
		FA 84	2	65	65	48	34	
		FA 85	1	1	0	1	0	
		FA 85	2	64	61	45	32	
		FA 87	1	2	1	0	0	
		FA 87	2	58	55	43	31	
		FA 88	1	1	0	0	0	
		FA 88	2	56	54	42	28	
		FA 97	1	2	0	0	0	
		FA 97	2	46	44	33	17	
		FA 98	1	1	0	0	0	
		FA 98	2	45	44	33	15	
		FA 99	1	1	0	1	0	
		FA 99	2	43	43	31	15	
		FA 100	1	3	0	0	0	
		FA 100	2	37	42	27	14	
		FA 103	1	1	0	0	0	
		FA 103	2	32	33	16	12	
		FA 104	1	1	0	0	0	
		FA 104	2	29	32	15	12	
Spontaneous tumor pct: 53% in ctrl.	-	Total	-	57	56	47	31	
PITUITARY	(1610)	FA 66	1	0	1	0	0	0.719 0.616 0.685
Schwannoma, Malignant	(23)	FA 66	2	88	95	73	57	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0	
PITUITARY	(1610)	FA 100	1	0	1	0	0	0.674 0.548 0.627
Pars Distalis, Carcinoma	(24)	FA 100	2	40	41	27	14	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	0	1	0	0	
KIDNEY	(1620)	IN 51-80	1	1	0	1	0	0.333 0.272 0.296
Tubular Adenoma	(25)	IN 51-80	2	25	32	36	37	
		IN 81-104	1	0	0	1	1	
		IN 81-104	2	45	40	37	25	
		IN 105-105	1	0	2	1	0	

Spontaneous tumor pct: <= 1% in ctrl.	IN 105-105 2	26 30 13 12	
	- Total -	1 2 3 1	
KIDNEY	(1620) FA 87 1	1 0 0 0	1.000 0.876 0.910
Mesenchymal Tumor, Malign	(26) FA 87 2	59 56 43 31	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	1 0 0 0	
KIDNEY	(1620) IN 105-105 1	0 1 0 0	0.690 0.556 0.632
Lipoma	(27) IN 105-105 2	26 31 14 12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 1 0 0	
KIDNEY	(1620) IN 81-104 1	0 1 0 0	0.698 0.610 0.679
Tubular Carcinoma	(28) IN 81-104 2	45 39 38 26	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 1 0 0	
PANCREAS	(1670) IN 51-80 1	1 1 0 0	0.998 0.998 0.998
Islet Cell Adenoma	(33) IN 51-80 2	25 31 37 37	
	IN 81-104 1	11 1 6 0	
	IN 81-104 2	34 39 32 26	
	IN 105-105 1	6 9 2 1	
	IN 105-105 2	20 23 12 11	
Spontaneous tumor pct: 17% in ctrl.	- Total -	18 11 8 1	
PANCREAS	(1670) IN 51-80 1	0 0 0 1	0.256 0.214 0.231
Acinar Cell Adenoma	(34) IN 51-80 2	26 32 37 36	
	IN 81-104 1	1 1 3 1	
	IN 81-104 2	44 39 35 25	
	IN 105-105 1	2 2 0 1	
	IN 105-105 2	24 30 14 11	
Spontaneous tumor pct: 3% in ctrl.	- Total -	3 3 3 3	
PANCREAS	(1670) IN 81-104 1	1 0 0 0	1.000 0.886 0.918
Acinar Cell Carcinoma	(35) IN 81-104 2	44 40 38 26	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	1 0 0 0	
PANCREAS	(1670) IN 81-104 1	0 2 0 0	0.336 0.246 0.282
Islet Cell Carcinoma	(36) IN 81-104 2	45 38 38 26	
	IN 105-105 1	0 0 0 1	
	IN 105-105 2	26 32 14 11	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 2 0 1	
LYMPH NODE, MESENTERIC	(1680) IN 51-80 1	0 1 0 0	0.941 0.899 0.920
Hemangioma	(37) IN 51-80 2	26 31 37 37	
	IN 81-104 1	1 0 0 0	
	IN 81-104 2	43 40 38 26	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	1 1 0 0	
LYMPH NODE, MESENTERIC	(1680) IN 81-104 1	0 1 0 0	0.476 0.353 0.405
Hemangiosarcoma	(38) IN 81-104 2	44 39 37 26	
	FA 101 1	0 0 1 0	
	FA 101 2	36 40 23 14	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 1 1 0	
LYMPH NODE, MESENTERIC	(1680) IN 105-105 1	0 1 0 0	0.690 0.556 0.632
Lymphangioma	(39) IN 105-105 2	26 31 14 12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 1 0 0	
SKIN	(1740) FA 59 1	0 0 1 0	0.432 0.273 0.338
Schwannoma, Malignant	(40) FA 59 2	91 99 80 64	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 0 1 0	
SKIN	(1740) IN 81-104 1	2 0 0 0	1.000 0.957 0.968
Squamous Papilloma	(41) IN 81-104 2	42 39 38 26	
Spontaneous tumor pct: 2% in ctrl.	- Total -	2 0 0 0	
SKIN	(1740) IN 81-104 1	1 0 1 0	0.224 0.158 0.182
Keratoacanthoma	(42) IN 81-104 2	43 39 37 26	
	IN 105-105 1	0 0 1 1	
	IN 105-105 2	26 32 13 11	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	1 0 2 1	
SKIN	(1740) IN 51-80 1	0 1 0 1	0.267 0.230 0.245
Fibroma	(43) IN 51-80 2	26 29 37 35	
	IN 81-104 1	0 2 0 1	
	IN 81-104 2	44 36 36 25	
	IN 105-105 1	2 3 1 1	
	IN 105-105 2	24 29 13 11	
	FA 79 1	0 1 0 0	
	FA 79 2	73 75 54 42	
	FA 93 1	0 0 1 0	
	FA 93 2	50 48 37 20	
	FA 95 1	0 1 0 0	
	FA 95 2	47 44 37 19	
	FA 99 1	0 0 1 0	
	FA 99 2	43 43 31 15	
Spontaneous tumor pct: 2% in ctrl.	- Total -	2 8 3 3	
SKIN	(1740) IN 105-105 1	0 1 0 0	0.899 0.817 0.852
Hemangiosarcoma	(45) IN 105-105 2	26 31 14 12	
	FA 99 1	1 0 0 0	
	FA 99 2	42 43 32 15	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	1 1 0 0	
SKIN	(1740) IN 105-105 1	1 1 1 0	0.669 0.614 0.640
Fibrosarcoma	(47) IN 105-105 2	25 31 13 12	
	FA 52 1	1 0 0 0	
	FA 52 2	95 102 89 73	
	FA 61 1	0 1 0 0	
	FA 61 2	89 97 76 63	
	FA 72 1	0 0 1 0	
	FA 72 2	83 82 62 49	
	FA 80 1	0 1 0 0	
	FA 80 2	71 72 54 41	
	FA 99 1	0 0 1 0	
	FA 99 2	43 43 31 15	
Spontaneous tumor pct: 2% in ctrl.	- Total -	2 3 3 0	
SKIN	(1740) IN 105-105 1	0 1 0 0	0.690 0.556 0.632
Lipoma	(48) IN 105-105 2	26 31 14 12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total -	0 1 0 0	

SKIN	(1740	}	IN 81-104	1	1	0	0	1	0.864	0.813	0.835
Basal Cell Adenoma	(49	}	IN 81-104	2	43	39	38	25			
			IN 105-105	1	2	1	0	0			
			IN 105-105	2	24	31	14	12			
Spontaneous tumor pct: 3%			- Total	-	3	1	0	1			
SKIN	(1740	}	IN 81-104	1	1	1	0	0	0.911	0.857	0.884
Sebaceous Cell Carcinoma	(50	}	IN 81-104	2	43	38	38	26			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	1	0	0			
SKIN	(1740	}	FA 102	1	1	0	0	0	1.000	0.862	0.901
Squamous Cell Carcinoma	(51	}	FA 102	2	34	36	20	12			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	0	0	0			
SKIN	(1740	}	IN 81-104	1	0	1	1	0	0.744	0.662	0.701
Sebaceous Cell Adenoma	(52	}	IN 81-104	2	44	38	37	26			
			IN 105-105	1	1	0	0	0			
			IN 105-105	2	25	32	14	12			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	1	1	0			
MAMMARY GLAND	(1750	}	IN 51-80	1	0	1	0	0	0.968	0.944	0.953
Fibroadenoma	(53	}	IN 51-80	2	26	31	37	37			
			IN 81-104	1	1	2	0	0			
			IN 81-104	2	43	38	38	26			
			FA 89	1	1	0	0	0			
			FA 89	2	54	53	42	28			
Spontaneous tumor pct: 2%			- Total	-	2	3	0	0			
MAMMARY GLAND	(1750	}	IN 81-104	1	0	0	0	1	0.174	0.057	0.082
Adenoma	(54	}	IN 81-104	2	45	40	38	25			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	0	0	1			
TONGUE	(1760	}	IN 105-105	1	0	1	0	0	0.690	0.556	0.632
Fibroma	(56	}	IN 105-105	2	26	31	14	12			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	2	0	0			
SKELETAL MUSCLE	(1770	}	FA 74	1	1	0	0	0	1.000	0.880	0.913
Rhabdomyosarcoma	(57	}	FA 74	2	82	81	60	47			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	0	0	0			
SKELETAL MUSCLE	(1770	}	IN 105-105	1	0	0	1	0	0.309	0.198	0.258
Lipoma	(59	}	IN 105-105	2	26	32	13	12			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	0	1	0			
THYROID	(1780	}	IN 51-80	1	0	0	1	1	0.648	0.602	0.622
C-Cell Adenoma	(60	}	IN 51-80	2	26	32	36	36			
			IN 81-104	1	3	2	1	1			
			IN 81-104	2	42	38	37	25			
			IN 105-105	1	0	4	0	0			
			IN 105-105	2	26	28	14	12			
Spontaneous tumor pct: 3%			- Total	-	3	6	2	2			
THYROID	(1780	}	IN 0-50	1	0	0	0	1	0.453	0.383	0.411
Follicular Cell Adenoma	(61	}	IN 0-50	2	11	16	30	37			
			IN 51-80	1	1	0	0	1			
			IN 51-80	2	25	32	37	36			
			IN 81-104	1	0	0	1	1			
			IN 81-104	2	45	40	37	25			
			IN 105-105	1	2	0	0	0			
			IN 105-105	2	24	32	14	12			
Spontaneous tumor pct: 3%			- Total	-	3	0	1	3			
THYROID	(1780	}	IN 81-104	1	1	0	0	0	1.000	0.886	0.918
C-Cell Carcinoma	(63	}	IN 81-104	2	44	40	38	26			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	0	0	0			
PARATHYROID	(1790	}	IN 81-104	1	1	1	1	1	0.673	0.603	0.635
Adenoma	(64	}	IN 81-104	2	34	36	32	23			
			IN 105-105	1	1	0	0	0			
			IN 105-105	2	21	28	12	12			
Spontaneous tumor pct: 2%			- Total	-	2	1	1	1			
HARDERIAN GLAND	(1840	}	IN 51-80	1	0	1	0	0	0.803	0.723	0.781
Carcinoma	(65	}	IN 51-80	2	26	31	37	37			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	1	0	0			
TESTIS	(1880	}	IN 51-80	1	1	0	1	1	0.299	0.268	0.280
Interstitial Cell Tumor	(66	}	IN 51-80	2	25	32	36	36			
			IN 81-104	1	2	4	6	3			
			IN 81-104	2	43	36	32	23			
			IN 105-105	1	5	2	0	2			
			IN 105-105	2	21	30	14	10			
Spontaneous tumor pct: 7%			- Total	-	8	6	7	6			
TESTIS	(1880	}	IN 81-104	1	0	1	0	0	0.698	0.610	0.679
Mesothelioma, Benign	(67	}	IN 81-104	2	45	39	38	26			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	1	0	0			
EPIDIDYMI	(1890	}	IN 81-104	1	0	1	0	0	0.698	0.610	0.679
Mesothelioma, Benign	(68	}	IN 81-104	2	45	39	38	26			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	1	0	0			
PROSTATE	(1920	}	IN 81-104	1	1	4	2	0	0.820	0.776	0.795
Adenoma	(69	}	IN 81-104	2	44	36	36	26			
			IN 105-105	1	1	0	0	0			
			IN 105-105	2	25	32	14	12			
Spontaneous tumor pct: 2%			- Total	-	2	4	2	0			
PROSTATE	(1920	}	FA 100	1	0	0	1	0	0.333	0.188	0.247
Carcinoma	(70	}	FA 100	2	40	42	26	14			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	0	1	0			
NASAL TURBINATE	(1990	}	FA 85	1	1	0	0	0	1.000	0.875	0.910
Schwannoma, Malignant	(90	}	FA 85	2	64	61	46	32			
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	1	0	0	0			
EAR	(2100	}	FA 72	1	0	1	0	0	0.491	0.369	0.420
Zymbal's Gland, Carcinoma	(91	}	FA 72	2	84	82	63	49			
			FA 90	1	0	0	1	0			

Spontaneous tumor pct: <= 1% in ctrl.	FA 90	2	54	50	39	26	
	- Total	-	0	1	1	0	
EAR (2100)	IN 105-105	1	0	0	0	1	0.081 0.036 0.048
Amelanotic Melanoma, Beni (92)	IN 105-105	2	26	32	14	11	
	FA 90	1	0	0	1	0	
	FA 90	2	54	50	39	26	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	0	0	1	1	
ORAL CAVITY (2140)	IN 105-105	1	0	1	0	0	0.690 0.556 0.632
Squamous Cell Carcinoma (93)	IN 105-105	2	26	31	14	12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	0	1	0	0	
SMALL INTESTINE (5555)	FA 102	1	0	1	0	0	0.653 0.530 0.609
Carcinoma (94)	FA 102	2	36	35	20	12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	0	1	0	0	
SYSTEMIC NEOPLASMS (7777)	FA 76	1	0	0	1	0	0.860 0.817 0.836
Histiocytic Sarcoma (100)	FA 76	2	77	79	58	45	
	FA 81	1	1	0	0	0	
	FA 81	2	70	72	52	38	
	FA 85	1	1	0	0	0	
	FA 85	2	64	61	46	32	
	FA 88	1	1	0	0	0	
	FA 88	2	56	54	42	28	
	FA 91	1	0	1	0	0	
	FA 91	2	52	48	39	25	
	FA 94	1	0	1	0	0	
	FA 94	2	49	47	37	19	
	FA 101	1	0	0	1	0	
	FA 101	2	36	40	23	14	
Spontaneous tumor pct: 3% in ctrl.	- Total	-	3	2	2	0	
SYSTEMIC NEOPLASMS (7777)	IN 81-104	1	0	1	0	0	0.200 0.128 0.152
Lymphoma (101)	IN 81-104	2	45	39	38	26	
	IN 105-105	1	0	0	0	1	
	IN 105-105	2	26	32	14	11	
	FA 29	1	0	0	1	0	
	FA 29	2	104	113	112	95	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	0	1	1	1	
SYSTEMIC NEOPLASMS (7777)	FA 103	1	1	0	0	0	1.000 0.855 0.895
Mononuclear Cell Leukemia (102)	FA 103	2	32	33	16	12	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	1	0	0	0	

APPEARS THIS WAY
ON ORIGINAL

Table 8a

Analysis of Carcinogenic Potential in Female Rat
 Test of Dose-Response (Tumor) Positive Linear Trend
 Dose Levels Included: CTRL LOW MED HIGH (0, 0.5, 1, 1.5)

Study No. 97095
 Run Date & Time: June 28, 2001 (17:07)
 Source: C:\N21-341\RAT\FEMALE\XanimalX.txt

Note: Dose Levels Included: CTRL LOW MED HIGH (0 0.5 1 1.5)
 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 TABLES	EXACT ASYMPTOTIC PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
BRAIN	(1510)	IN 81-104	1	0 0 1 0	
Astrocytoma, Malignant	(1)	IN 81-104	2	47 51 28 13	
		IN 105-105	1	1 0 0 0	
		IN 105-105	2	18 32 19 0	
Spontaneous tumor pct: 1%		in ctrl. - Total	-	1 0 1 0	
THYMUS	(1550)	IN 51-80	1	0 1 0 0	0.720 0.612 0.892
Thymoma, Benign	(10)	IN 51-80	2	31 33 28 18	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0	
LIVER	(1580)	IN 81-104	1	0 0 1 0	0.694 0.625 0.782
Hepatocellular Adenoma	(15)	IN 81-104	2	47 51 28 13	
		IN 105-105	1	1 1 1 0	
		IN 105-105	2	18 31 18 0	
		IN INTERIM	1	1 0 0 0	
		IN INTERIM	2	9 0 0 12	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2 1 2 0	
SPLEEN	(1590)	FA 85	1	0 1 0 0	0.668 0.536 0.866
Sarcoma, NOS	(17)	FA 85	2	70 74 43 23	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0 0	
ADRENAL	(1600)	IN 51-80	1	0 1 1 1	0.138 0.114 0.164
Pheochromocytoma, Benign	(18)	IN 51-80	2	30 35 29 18	
		IN 81-104	1	2 7 4 0	
		IN 81-104	2	45 44 25 13	
		IN 105-105	1	2 5 4 0	
		IN 105-105	2	17 27 15 0	
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4 13 9 1	
ADRENAL	(1600)	IN 81-104	1	0 0 1 0	0.671 0.599 0.761
Pheochromocytoma, Maligna	(19)	IN 81-104	2	47 51 28 12	
		FA 56	1	1 0 0 0	
		FA 56	2	103 117 76 41	
		FA 62	1	1 0 0 0	
		FA 62	2	96 109 68 38	
		FA 77	1	1 0 0 0	
		FA 77	2	78 90 51 28	
		FA 97	1	0 0 0 1	
		FA 97	2	42 51 27 12	
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3 0 1 1	
ADRENAL	(1600)	IN 51-80	1	1 1 0 1	0.430 0.376 0.490
Cortex, Adenoma	(20)	IN 51-80	2	29 35 30 18	
		IN 81-104	1	1 1 2 1	
		IN 81-104	2	46 50 27 12	
		IN 105-105	1	1 2 1 0	
		IN 105-105	2	18 30 18 0	
		IN INTERIM	1	1 0 0 0	
		IN INTERIM	2	9 0 0 12	
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4 4 3 2	
ADRENAL	(1600)	IN 81-104	1	1 0 0 0	0.905 0.858 0.934
Cortex, Carcinoma	(21)	IN 81-104	2	44 50 28 13	
		IN 105-105	1	0 1 0 0	
		IN 105-105	2	19 31 19 0	
		FA 95	1	1 0 0 0	
		FA 95	2	49 57 28 13	
		FA 96	1	1 0 0 0	
		FA 96	2	44 52 27 13	
		FA 103	1	0 0 1 0	
		FA 103	2	31 35 21 12	
		FA 104	1	0 1 0 0	
		FA 104	2	30 34 20 12	
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3 2 1 0	
PITUITARY	(1610)	IN 51-80	1	9 13 6 3	0.516 0.502 0.534
Pars Distalis, Adenoma	(22)	IN 51-80	2	10 11 9 9	
		IN 81-104	1	13 13 13 4	
		IN 81-104	2	7 7 1 3	
		IN 105-105	1	17 28 17 0	
		IN 105-105	2	2 2 2 0	
		IN INTERIM	1	9 0 0 9	
		IN INTERIM	2	1 0 0 3	
		FA 56	1	0 1 0 0	
		FA 56	2	104 116 76 41	
		FA 57	1	0 1 0 0	
		FA 57	2	103 115 76 41	
		FA 58	1	1 0 0 0	
		FA 58	2	102 115 75 40	
		FA 59	1	1 0 0 0	
		FA 59	2	101 114 75 40	

FA 60	1	2	1	0	0
FA 60	2	99112	72	39	
FA 61	1	0	0	2	1
FA 61	2	98110	69	38	
FA 62	1	1	0	2	0
FA 62	2	96109	66	38	
FA 63	1	0	0	1	0
FA 63	2	95108	65	38	
FA 64	1	0	1	0	0
FA 64	2	93107	65	38	
FA 65	1	0	0	1	1
FA 65	2	93107	63	36	
FA 67	1	0	0	1	0
FA 67	2	91107	62	36	
FA 68	1	1	0	0	0
FA 68	2	90106	62	35	
FA 69	1	1	0	1	0
FA 69	2	89106	61	34	
FA 70	1	1	0	0	2
FA 70	2	86106	61	32	
FA 71	1	1	0	0	1
FA 71	2	85105	60	31	
FA 72	1	1	1	1	0
FA 72	2	84102	57	31	
FA 73	1	0	1	0	1
FA 73	2	82	99	56	30
FA 74	1	1	1	1	0
FA 74	2	80	96	54	30
FA 75	1	0	1	0	0
FA 75	2	80	92	54	29
FA 76	1	0	1	2	0
FA 76	2	79	90	52	28
FA 77	1	0	1	1	0
FA 77	2	79	89	50	28
FA 78	1	0	1	1	0
FA 78	2	78	87	49	27
FA 79	1	0	1	0	0
FA 79	2	77	85	49	27
FA 80	1	0	0	1	1
FA 80	2	77	84	48	25
FA 81	1	0	1	1	0
FA 81	2	76	82	47	25
FA 82	1	1	1	1	0
FA 82	2	72	80	44	25
FA 83	1	0	3	0	2
FA 83	2	72	77	44	23
FA 84	1	0	1	1	0
FA 84	2	72	75	43	23
FA 85	1	3	1	1	0
FA 85	2	67	74	42	23
FA 86	1	0	2	0	1
FA 86	2	66	71	42	21
FA 87	1	1	2	1	1
FA 87	2	65	68	40	19
FA 88	1	1	2	1	0
FA 88	2	63	66	39	18
FA 89	1	1	0	2	0
FA 89	2	62	66	37	16
FA 90	1	0	1	0	0
FA 90	2	62	65	37	16
FA 91	1	3	1	1	0
FA 91	2	59	64	35	15
FA 92	1	2	0	2	1
FA 92	2	56	63	31	14
FA 93	1	1	1	0	1
FA 93	2	52	62	31	13
FA 94	1	1	3	1	0
FA 94	2	50	58	28	13
FA 95	1	1	4	1	0
FA 95	2	49	53	27	13
FA 96	1	2	0	0	0
FA 96	2	43	52	27	13
FA 97	1	1	0	0	0
FA 97	2	41	51	27	13
FA 98	1	1	2	0	0
FA 98	2	39	48	26	12
FA 99	1	2	2	1	0
FA 99	2	36	45	25	12
FA 100	1	2	1	1	0
FA 100	2	34	42	23	12
FA 101	1	2	1	0	0
FA 101	2	32	38	23	12
FA 102	1	1	0	0	0
FA 102	2	31	37	23	12
FA 104	1	1	2	0	0
FA 104	2	29	33	20	12
FA 105	1	0	2	0	0
FA 105	2	29	30	19	12
- Total	-	86	99	66	29

Spontaneous tumor pct: 87% in ctrl. - Total

PITUITARY	(1610	)	IN 105-105	1	0	1	0	0	
Pars Distalis, Carcinoma	(24	)	IN 105-105	2	19	31	19	0	0.670 0.534 0.818
				1	0	1	0	0	
				2	36	42	24	12	

Spontaneous tumor pct: <= 1% in ctrl. - Total

KIDNEY	(1620	)	IN 81-104	1	1	1	0	0	
Tubular Adenoma	(25	)	IN 81-104	2	46	50	29	13	0.888 0.796 0.942
				1	1	1	0	0	
				2	1	1	0	0	

KIDNEY	(1620	)	IN 51-80	1	0	0	0	1	
Lipoma	(27	)	IN 51-80	2	31	36	30	18	0.163 0.052 0.256
				1	0	0	0	1	
				2	0	0	0	1	

KIDNEY	(1620	)	IN 81-104	1	0	1	0	0	
Tubular Carcinoma	(28	)	IN 81-104	2	47	50	29	13	0.908 0.809 0.956
				1	1	0	0	0	
				2	18	32	19	0	

Spontaneous tumor pct: 1% in ctrl. - Total

KIDNEY	(1620)	IN INTERIM 1	1	0	0	0	1.000	0.863	0.961
Liposarcoma	(29)	IN INTERIM 2	9	0	0	12			
Spontaneous tumor pct: 1%	in ctrl.	- Total	1	0	0	0			
STOMACH	(1650)	IN 51-80 1	0	0	0	1	0.165	0.053	0.259
Glandular, Squamous Papil	(30)	IN 51-80 2	30	36	30	18			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	0	1			
STOMACH	(1650)	FA 83 1	0	1	0	0	0.674	0.540	0.868
Leiomyosarcoma	(31)	FA 83 2	72	79	44	25			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	1	0	0			
STOMACH	(1650)	IN 105-105 1	0	0	1	0	0.271	0.087	0.500
Nonglandular, Squamous Ce	(32)	IN 105-105 2	19	32	18	0			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	1	0			
PANCREAS	(1670)	IN 81-104 1	3	1	0	0	0.847	0.799	0.888
Islet Cell Adenoma	(33)	IN 81-104 2	44	50	29	13			
		IN 105-105 1	2	2	3	0			
		IN 105-105 2	17	30	16	0			
Spontaneous tumor pct: 5%	in ctrl.	- Total	5	3	3	0			
PANCREAS	(1670)	IN 81-104 1	1	0	0	0	1.000	0.866	0.984
Acinar Cell Adenoma	(34)	IN 81-104 2	46	51	29	13			
Spontaneous tumor pct: 1%	in ctrl.	- Total	1	0	0	0			
LYMPH NODE, MESENTERIC	(1680)	IN 51-80 1	1	0	0	0	0.694	0.593	0.806
Hemangioma	(37)	IN 51-80 2	30	36	30	19			
		IN 81-104 1	0	1	0	0			
		IN 81-104 2	47	50	29	13			
		IN 105-105 1	0	0	1	0			
		IN 105-105 2	19	31	18	0			
Spontaneous tumor pct: 1%	in ctrl.	- Total	1	1	1	0			
SKIN	(1740)	FA 90 1	0	0	1	0	0.297	0.158	0.521
Schwannoma, Malignant	(40)	FA 90 2	60	65	36	16			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	1	0			
SKIN	(1740)	IN 105-105 1	1	0	0	0	1.000	0.912	0.996
Keratoacanthoma	(42)	IN 105-105 2	18	32	19	0			
Spontaneous tumor pct: 1%	in ctrl.	- Total	1	0	0	0			
SKIN	(1740)	IN 81-104 1	0	0	1	0	0.867	0.776	0.929
Fibroma	(43)	IN 81-104 2	45	49	28	13			
		IN 105-105 1	2	0	0	0			
		IN 105-105 2	17	32	19	0			
Spontaneous tumor pct: 2%	in ctrl.	- Total	2	0	1	0			
SKIN	(1740)	IN 81-104 1	1	0	0	0	1.000	0.868	0.984
Amelanotic Melanoma, Beni	(44)	IN 81-104 2	44	49	29	13			
Spontaneous tumor pct: 1%	in ctrl.	- Total	1	0	0	0			
SKIN	(1740)	FA 69 1	1	0	0	0	1.000	0.946	0.990
Sarcoma, NOS	(46)	FA 69 2	88	104	62	34			
		FA 84 1	1	0	0	0			
		FA 84 2	69	75	44	23			
Spontaneous tumor pct: 2%	in ctrl.	- Total	2	0	0	0			
SKIN	(1740)	IN 51-80 1	0	1	0	0	0.517	0.419	0.642
Fibrosarcoma	(47)	IN 51-80 2	31	34	29	19			
		FA 61 1	0	1	0	0			
		FA 61 2	97	107	71	39			
		FA 64 1	0	0	1	0			
		FA 64 2	92	106	64	38			
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	2	1	0			
MAMMARY GLAND	(1750)	IN 51-80 1	4	3	3	2	0.872	0.861	0.881
Fibroadenoma	(53)	IN 51-80 2	21	25	25	17			
		IN 81-104 1	8	19	5	2			
		IN 81-104 2	27	16	14	9			
		IN 105-105 1	14	24	12	0			
		IN 105-105 2	5	8	7	0			
		IN INTERIM 1	5	0	0	6			
		IN INTERIM 2	5	0	0	6			
		FA 56 1	0	1	0	0			
		FA 56 2	104	115	76	41			
		FA 58 1	1	0	0	0			
		FA 58 2	102	114	75	40			
		FA 59 1	1	0	0	0			
		FA 59 2	101	113	75	40			
		FA 60 1	1	0	1	0			
		FA 60 2	100	112	71	39			
		FA 71 1	0	1	0	0			
		FA 71 2	86	103	60	32			
		FA 72 1	1	2	0	0			
		FA 72 2	84	100	58	31			
		FA 74 1	0	2	0	0			
		FA 74 2	80	94	55	30			
		FA 75 1	1	0	0	0			
		FA 75 2	78	92	54	29			
		FA 76 1	0	1	0	0			
		FA 76 2	78	89	54	28			
		FA 77 1	1	0	0	0			
		FA 77 2	77	89	51	28			
		FA 79 1	0	1	0	0			
		FA 79 2	76	84	49	27			
		FA 80 1	0	0	1	0			
		FA 80 2	76	83	48	26			
		FA 81 1	1	1	1	0			
		FA 81 2	74	81	47	25			
		FA 85 1	0	1	0	0			
		FA 85 2	69	74	43	23			
		FA 86 1	0	1	0	0			
		FA 86 2	65	72	42	22			
		FA 87 1	0	3	0	0			
		FA 87 2	65	69	41	20			
		FA 88 1	0	1	1	0			
		FA 88 2	63	67	39	18			
		FA 89 1	1	0	0	0			
		FA 89 2	61	66	39	16			

FA 90	1	0	0	0	1	
FA 90	2	61	66	37	15	
FA 91	1	0	0	2	0	
FA 91	2	61	65	34	15	
FA 92	1	1	0	0	1	
FA 92	2	56	63	33	14	
FA 93	1	0	1	0	0	
FA 93	2	52	62	31	14	
FA 94	1	1	1	0	0	
FA 94	2	49	60	29	13	
FA 95	1	1	2	1	0	
FA 95	2	48	55	27	13	
FA 97	1	2	1	1	0	
FA 97	2	40	50	26	13	
FA 98	1	0	1	0	0	
FA 98	2	40	49	26	12	
FA 99	1	0	3	1	0	
FA 99	2	38	44	25	12	
FA 100	1	1	1	1	0	
FA 100	2	35	42	23	12	
FA 101	1	1	0	0	0	
FA 101	2	33	39	23	12	
FA 102	1	1	0	1	0	
FA 102	2	31	37	22	12	
FA 103	1	1	0	0	0	
FA 103	2	30	35	22	12	
FA 104	1	0	0	1	0	
FA 104	2	30	35	19	12	
Spontaneous tumor pct: 48% in ctrl.	-	Total	-	48	69	32 12
MAMMARY GLAND	(1750	)	IN 81-104	1	1	2 0 0
Adenoma	(54	)	IN 81-104	2	45	47 29 13
			IN 105-105	1	0	1 1 0
			IN 105-105	2	19	31 18 0
			FA 75	1	0	1 0 0
			FA 75	2	79	91 54 29
			FA 95	1	0	1 0 0
			FA 95	2	49	56 28 13
Spontaneous tumor pct: 1% in ctrl.	-	Total	-	1	5	1 0
MAMMARY GLAND	(1750	)	IN 51-80	1	3	1 1 2
Carcinoma	(55	)	IN 51-80	2	20	21 27 16
			IN 81-104	1	5	4 1 0
			IN 81-104	2	32	39 20 11
			IN 105-105	1	9	9 8 0
			IN 105-105	2	10	23 11 0
			IN INTERIM	1	5	0 0 0
			IN INTERIM	2	5	0 0 12
			FA 36	1	1	0 0 0
			FA 36	2	106	120 80 47
			FA 48	1	0	1 0 0
			FA 48	2	106	118 78 45
			FA 52	1	0	1 0 0
			FA 52	2	106	117 77 44
			FA 57	1	0	0 0 1
			FA 57	2	103	115 76 40
			FA 58	1	0	1 0 0
			FA 58	2	103	113 75 40
			FA 61	1	0	1 1 0
			FA 61	2	98	108 70 39
			FA 62	1	0	1 0 0
			FA 62	2	97	107 68 38
			FA 66	1	2	0 0 0
			FA 66	2	91	106 63 36
			FA 70	1	1	0 0 0
			FA 70	2	86	105 61 34
			FA 71	1	0	1 0 0
			FA 71	2	86	103 60 32
			FA 72	1	2	2 0 0
			FA 72	2	83	100 58 31
			FA 73	1	0	1 0 0
			FA 73	2	81	98 56 31
			FA 74	1	0	4 0 0
			FA 74	2	80	92 55 30
			FA 75	1	1	1 0 0
			FA 75	2	78	91 54 29
			FA 76	1	0	1 1 0
			FA 76	2	78	89 53 28
			FA 77	1	1	0 0 0
			FA 77	2	77	89 51 28
			FA 78	1	1	0 0 0
			FA 78	2	76	87 50 27
			FA 81	1	1	0 0 0
			FA 81	2	74	82 48 25
			FA 85	1	1	0 0 1
			FA 85	2	68	75 43 22
			FA 86	1	0	0 0 1
			FA 86	2	65	73 42 21
			FA 87	1	0	0 1 0
			FA 87	2	65	70 40 20
			FA 88	1	0	0 1 0
			FA 88	2	63	68 39 18
			FA 91	1	0	0 1 0
			FA 91	2	61	65 35 15
			FA 92	1	1	0 0 0
			FA 92	2	56	63 33 15
			FA 93	1	0	0 1 0
			FA 93	2	52	63 30 14
			FA 94	1	0	1 0 0
			FA 94	2	50	60 29 13
			FA 95	1	2	0 1 0
			FA 95	2	47	57 27 13
			FA 96	1	1	0 0 0
			FA 96	2	44	52 27 13
			FA 98	1	0	1 0 0
			FA 98	2	40	49 26 12
			FA 99	1	0	3 1 0
			FA 99	2	38	44 25 12
			FA 100	1	1	1 0 0
			FA 100	2	35	42 24 12

0.630 0.560 0.716

0.995 0.993 0.995

	FA 101	1	1	1	0	0	
	FA 101	2	33	38	23	12	
	FA 102	1	0	0	1	0	
	FA 102	2	32	37	22	12	
	FA 103	1	1	0	0	0	
	FA 103	2	30	35	22	12	
	FA 104	1	0	0	1	0	
	FA 104	2	30	35	19	12	
Spontaneous tumor pct: 40%	in ctrl.	-	40	36	20	5	
SKELETAL MUSCLE	(1770)	FA 41	1	0	1	0	0
Sarcoma, NOS	(58)	FA 41	2	107	120	79	46
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	1	0	0	0.696 0.571 0.879
THYROID	(1780)	IN 51-80	1	1	1	1	
C-Cell Adenoma	(60)	IN 51-80	2	30	35	29	18
		IN 81-104	1	2	2	1	1
		IN 81-104	2	45	49	28	12
		IN 105-105	1	0	1	2	0
		IN 105-105	2	19	31	17	0
		IN INTERIM	1	1	0	0	1
		IN INTERIM	2	9	0	0	11
Spontaneous tumor pct: 4%	in ctrl.	-	4	4	4	3	0.253 0.213 0.295
THYROID	(1780)	IN 51-80	1	1	0	0	0
Follicular Cell Adenoma	(61)	IN 51-80	2	30	36	30	19
		IN 81-104	1	0	1	0	0
		IN 81-104	2	47	50	29	13
Spontaneous tumor pct: 1%	in ctrl.	-	1	1	0	0	0.910 0.835 0.953
THYROID	(1780)	IN 81-104	1	0	0	1	0
Follicular Cell Carcinoma	(62)	IN 81-104	2	46	51	28	13
		FA 93	1	1	0	0	0
		FA 93	2	52	63	31	14
Spontaneous tumor pct: 1%	in ctrl.	-	1	0	1	0	0.640 0.530 0.795
THYROID	(1780)	IN 81-104	1	0	1	0	0
C-Cell Carcinoma	(63)	IN 81-104	2	46	50	29	13
		FA 93	1	1	0	0	0
		FA 93	2	52	63	31	14
Spontaneous tumor pct: 1%	in ctrl.	-	1	1	0	0	0.891 0.795 0.942
URINARY BLADDER	(1940)	IN 105-105	1	0	1	0	0
Transitional Epithelium,	(71)	IN 105-105	2	19	31	19	0
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	1	0	0	0.728 0.500 0.912
OVARY	(1950)	IN 81-104	1	0	1	0	0
Granulosa Cell Tumor, Ben	(72)	IN 81-104	2	47	50	29	13
		IN 105-105	1	0	0	1	0
		IN 105-105	2	19	32	18	0
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	1	1	0	0.342 0.217 0.518
OVARY	(1950)	IN 105-105	1	0	0	1	0
Sertoli Cell Tumor, Benig	(73)	IN 105-105	2	19	32	18	0
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	0	1	0	0.271 0.087 0.500
OVARY	(1950)	IN 105-105	1	0	1	0	0
Luteoma, Benign	(74)	IN 105-105	2	19	31	19	0
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	1	0	0	0.728 0.500 0.912
OVARY	(1950)	IN 105-105	1	0	1	0	0
Tubulostromal Adenoma	(75)	IN 105-105	2	19	31	19	0
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	1	0	0	0.728 0.500 0.912
OVARY	(1950)	IN INTERIM	1	0	0	0	1
Thecoma, Benign	(76)	IN INTERIM	2	10	0	0	11
Spontaneous tumor pct: <= 1%	in ctrl.	-	0	0	0	1	0.545 0.180 0.403
UTERUS	(1960)	FA 101	1	1	0	0	0
Schwannoma, Malignant	(77)	FA 101	2	33	39	23	12
Spontaneous tumor pct: 1%	in ctrl.	-	1	0	0	0	1.000 0.873 0.984
UTERUS	(1960)	IN 81-104	1	1	0	0	0
Squamous Papilloma	(78)	IN 81-104	2	46	51	29	13
Spontaneous tumor pct: 1%	in ctrl.	-	1	0	0	0	1.000 0.866 0.984
UTERUS	(1960)	IN 81-104	1	1	0	0	0
Granular Cell Tumor, Beni	(79)	IN 81-104	2	46	51	29	13
		IN 105-105	1	0	1	0	0
		IN 105-105	2	19	31	19	0
Spontaneous tumor pct: 1%	in ctrl.	-	1	1	0	0	0.908 0.809 0.956
UTERUS	(1960)	IN 81-104	1	0	1	1	0
Leiomyoma	(80)	IN 81-104	2	47	50	28	13
		IN 105-105	1	1	1	0	0
		IN 105-105	2	18	31	19	0
Spontaneous tumor pct: 1%	in ctrl.	-	1	2	1	0	0.627 0.526 0.744
UTERUS	(1960)	IN 51-80	1	0	2	2	2
Endometrial Stroma) Polyp	(81)	IN 51-80	2	31	34	28	17
		IN 81-104	1	4	4	1	2
		IN 81-104	2	43	47	28	11
		IN 105-105	1	3	2	1	0
		IN 105-105	2	16	30	18	0
		IN INTERIM	1	1	0	0	2
		IN INTERIM	2	9	0	0	10
Spontaneous tumor pct: 8%	in ctrl.	-	8	8	4	6	0.269 0.237 0.303
UTERUS	(1960)	IN 105-105	1	1	0	0	0
Endometrial Carcinoma	(82)	IN 105-105	2	18	32	19	0
Spontaneous tumor pct: 1%	in ctrl.	-	1	0	0	0	1.000 0.912 0.996
UTERUS	(1960)	FA 61	1	1	0	0	0
Endometrial Stromal Sarco	(83)	FA 61	2	98	110	71	39
		FA 63	1	1	0	0	0
		FA 63	2	95	108	66	38
		FA 91	1	1	0	0	0
		FA 91	2	61	65	36	15
		FA 97	1	1	0	0	0
		FA 97	2	41	51	27	13

Spontaneous tumor pct: 4%	in ctrl.	-	Total	-	4	0	0	0	
CERVIX	(1970	}	IN 51-80	1	0	1	0	0	0.732 0.620 0.897
Leiomyoma	(84	}	IN 51-80	2	31	35	30	19	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0	0	
CERVIX	(1970	}	IN 105-105	1	1	1	0	0	0.929 0.833 0.973
Stromal Polyp	(85	}	IN 105-105	2	18	31	19	0	
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	1	0	0	
VAGINA	(1980	}	FA 99	1	0	0	1	0	0.308 0.170 0.540
Schwannoma, Malignant	(86	}	FA 99	2	38	47	25	12	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	0	1	0	
VAGINA	(1980	}	IN 81-104	1	0	1	0	0	0.640 0.516 0.773
Granular Cell Tumor, Beni	(87	}	IN 81-104	2	47	50	29	13	
		}	IN 105-105	1	1	0	1	0	
		}	IN 105-105	2	18	32	18	0	
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	1	1	0	
VAGINA	(1980	}	IN 81-104	1	0	1	0	0	0.362 0.230 0.431
Leiomyoma	(88	}	IN 81-104	2	47	50	29	13	
		}	IN INTERIM	1	0	0	0	1	
		}	IN INTERIM	2	10	0	0	11	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0	1	
VAGINA	(1980	}	IN 105-105	1	1	0	0	0	1.000 0.912 0.996
Stromal Polyp	(89	}	IN 105-105	2	18	32	19	0	
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0	0	
SMALL INTESTINE	(5555	}	FA 100	1	0	1	0	0	0.687 0.543 0.874
Carcinoma	(94	}	FA 100	2	36	42	24	12	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0	0	
SMALL INTESTINE	(5555	}	IN 81-104	1	1	0	0	0	1.000 0.866 0.984
Leiomyoma	(95	}	IN 81-104	2	46	51	29	13	
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0	0	
SMALL INTESTINE	(5555	}	IN 105-105	1	0	0	1	0	0.271 0.087 0.500
Leiomyosarcoma	(96	}	IN 105-105	2	19	32	18	0	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	0	1	0	
LARGE INTESTINE	(6666	}	IN 51-80	1	1	0	0	0	1.000 0.965 0.995
Granular Cell Tumor, Beni	(97	}	IN 51-80	2	30	36	30	19	
		}	IN 105-105	1	1	0	0	0	
		}	IN 105-105	2	18	32	19	0	
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	0	0	0	
LARGE INTESTINE	(6666	}	IN 81-104	1	0	0	1	0	0.300 0.161 0.523
Leiomyoma	(98	}	IN 81-104	2	47	51	28	13	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	0	1	0	
LARGE INTESTINE	(6666	}	IN 105-105	1	0	1	0	0	0.728 0.500 0.912
Leiomyosarcoma	(99	}	IN 105-105	2	19	31	19	0	
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0	0	
SYSTEMIC NEOPLASMS	(7777	}	IN 81-104	1	0	1	0	0	0.804 0.746 0.860
Histiocytic Sarcoma	(100	}	IN 81-104	2	46	48	29	13	
		}	FA 76	1	0	0	1	0	
		}	FA 76	2	79	91	53	28	
		}	FA 90	1	0	1	0	0	
		}	FA 90	2	62	65	37	16	
		}	FA 96	1	1	0	0	0	
		}	FA 96	2	44	52	27	13	
		}	FA 102	1	0	1	0	0	
		}	FA 102	2	32	36	23	12	
		}	FA 105	1	1	0	0	0	
		}	FA 105	2	28	32	19	12	
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	3	1	0	
SYSTEMIC NEOPLASMS	(7777	}	IN 81-104	1	0	1	0	0	0.796 0.738 0.853
Lymphoma	(101	}	IN 81-104	2	46	49	29	13	
		}	IN 105-105	1	0	1	1	0	
		}	IN 105-105	2	19	30	18	0	
		}	FA 28	1	1	0	0	0	
		}	FA 28	2	108	121	83	49	
		}	FA 95	1	1	0	0	0	
		}	FA 95	2	49	57	28	13	
		}	FA 100	1	0	1	0	0	
		}	FA 100	2	36	42	24	12	
		}	FA 105	1	0	1	0	0	
		}	FA 105	2	29	31	19	12	
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	4	1	0	
SYSTEMIC NEOPLASMS	(7777	}	IN 105-105	1	1	0	0	0	1.000 0.912 0.996
Mononuclear Cell Leukemia	(102	}	IN 105-105	2	18	32	19	0	
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0	0	

Table 8b

Analysis of Carcinogenic Potential in Female Rat
Test of Dose-Response (Tumor) Positive Linear Trend
Dose Levels Included: CTRL LOW MED (0, 0.5, 1)

Study No. 97095
Run Date & Time: June 28, 2001 (17:25)
Source: C:\N21-341\RAT\FEMALE\Xanim1X.txt

Note: Dose Levels Included: CTRL1 LOW MED (0 0.5 1)
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 TABLES	EXACT PROB	ASYMP PROB	ASYMP /CONT	PROB CORR
BRAIN	(1510)	IN 81-104	1	0 0 1				
Astrocytoma, Malignant	(1)	IN 81-104	2	47 51 28				
		IN 105-105	1	1 0 0				
		IN 105-105	2	18 32 19				
Spontaneous tumor pct: 1%		in ctrl. - Total	-	1 0 1				
THYMUS	(1550)	IN 51-80	1	0 1 0	0.666	0.483	0.888	
Thymoma, Benign	(10)	IN 51-80	2	31 33 28				
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0				
LIVER	(1580)	IN 81-104	1	0 0 1	0.332	0.218	0.461	
Hepatocellular Adenoma	(15)	IN 81-104	2	47 51 28				
		IN 105-105	1	1 1 1				
		IN 105-105	2	18 31 18				
		IN INTERIM 1	1	1 0 0				
		IN INTERIM 2	2	9 0 0				
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2 1 2				
SPLEEN	(1590)	FA 85	1	0 1 0	0.627	0.425	0.869	
Sarcoma, NOS	(17)	FA 85	2	70 74 43				
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0 1 0				
ADRENAL	(1600)	IN 51-80	1	0 1 1	0.040	0.029	0.053	
Pheochromocytoma, Benign	(18)	IN 51-80	2	30 35 29				
		IN 81-104	1	2 7 4				
		IN 81-104	2	45 44 25				
		IN 105-105	1	2 5 4				
		IN 105-105	2	17 27 15				
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4 13 9				
ADRENAL	(1600)	IN 81-104	1	0 0 1	0.909	0.841	0.950	
Pheochromocytoma, Maligna	(19)	IN 81-104	2	47 51 28				
		FA 56	1	1 0 0				
		FA 56	2	103 117 76				
		FA 62	1	1 0 0				
		FA 62	2	96 109 68				
		FA 77	1	1 0 0				
		FA 77	2	78 90 51				
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3 0 1				
ADRENAL	(1600)	IN 51-80	1	1 1 0	0.486	0.405	0.572	
Cortex, Adenoma	(20)	IN 51-80	2	29 35 30				
		IN 81-104	1	1 1 2				
		IN 81-104	2	46 50 27				
		IN 105-105	1	1 2 1				
		IN 105-105	2	18 30 18				
		IN INTERIM 1	1	1 0 0				
		IN INTERIM 2	2	9 0 0				
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4 4 3				
ADRENAL	(1600)	IN 81-104	1	1 0 0	0.838	0.765	0.897	
Cortex, Carcinoma	(21)	IN 81-104	2	44 50 28				
		IN 105-105	1	0 1 0				
		IN 105-105	2	19 31 19				
		FA 95	1	1 0 0				
		FA 95	2	49 57 28				
		FA 96	1	1 0 0				
		FA 96	2	44 52 27				
		FA 103	1	0 0 1				
		FA 103	2	31 35 21				
		FA 104	1	0 1 0				
		FA 104	2	30 34 20				
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3 2 1				
PITUITARY	(1610)	IN 51-80	1	9 13 6	0.151	0.138	0.164	
Pars Distalis, Adenoma	(22)	IN 51-80	2	10 11 9				
		IN 81-104	1	13 13 13				
		IN 81-104	2	7 7 1				
		IN 105-105	1	17 28 17				
		IN 105-105	2	2 2 2				
		IN INTERIM 1	1	9 0 0				
		IN INTERIM 2	2	1 0 0				
		FA 56	1	0 1 0				
		FA 56	2	104 116 76				
		FA 57	1	0 1 0				
		FA 57	2	103 115 76				
		FA 58	1	1 0 0				
		FA 58	2	102 115 75				
		FA 59	1	1 0 0				
		FA 59	2	101 114 75				
		FA 60	1	2 1 0				

FA 60	2	99112	72	
FA 61	1	0	0	2
FA 61	2	98110	69	
FA 62	1	1	0	2
FA 62	2	96109	66	
FA 63	1	0	0	1
FA 63	2	95108	65	
FA 64	1	0	1	0
FA 64	2	93107	65	
FA 65	1	0	0	1
FA 65	2	93107	63	
FA 67	1	0	0	1
FA 67	2	91107	62	
FA 68	1	1	0	0
FA 68	2	90106	62	
FA 69	1	1	0	1
FA 69	2	89106	61	
FA 70	1	1	0	0
FA 70	2	86106	61	
FA 71	1	1	0	0
FA 71	2	85105	60	
FA 72	1	1	1	1
FA 72	2	84102	57	
FA 73	1	0	1	0
FA 73	2	82	99	56
FA 74	1	1	1	1
FA 74	2	80	96	54
FA 75	1	0	1	0
FA 75	2	80	92	54
FA 76	1	0	1	2
FA 76	2	79	90	52
FA 77	1	0	1	1
FA 77	2	79	89	50
FA 78	1	0	1	1
FA 78	2	78	87	49
FA 79	1	0	1	0
FA 79	2	77	85	49
FA 80	1	0	0	1
FA 80	2	77	84	48
FA 81	1	0	1	1
FA 81	2	76	82	47
FA 82	1	1	1	1
FA 82	2	72	80	44
FA 83	1	0	3	0
FA 83	2	72	77	44
FA 84	1	0	1	1
FA 84	2	72	75	43
FA 85	1	3	1	3
FA 85	2	67	74	42
FA 86	1	0	2	0
FA 86	2	66	71	42
FA 87	1	1	2	1
FA 87	2	65	68	40
FA 88	1	1	2	1
FA 88	2	63	66	39
FA 89	1	1	0	2
FA 89	2	62	66	37
FA 90	1	0	1	0
FA 90	2	62	65	37
FA 91	1	3	1	1
FA 91	2	59	64	35
FA 92	1	2	0	2
FA 92	2	56	63	31
FA 93	1	1	1	0
FA 93	2	52	62	31
FA 94	1	1	3	1
FA 94	2	50	58	28
FA 95	1	1	4	1
FA 95	2	49	53	27
FA 96	1	2	0	0
FA 96	2	43	52	27
FA 97	1	1	0	0
FA 97	2	41	51	27
FA 98	1	1	2	0
FA 98	2	39	48	26
FA 99	1	2	2	1
FA 99	2	36	45	25
FA 100	1	2	1	1
FA 100	2	34	42	23
FA 101	1	2	1	0
FA 101	2	32	38	23
FA 102	1	1	0	0
FA 102	2	31	37	23
FA 104	1	1	2	0
FA 104	2	29	33	20
FA 105	1	0	2	0
FA 105	2	29	30	19
Spontaneous tumor pct: 87% in ctrl. - Total	-	86	99	66
PITUITARY (1610) IN 105-105	1	0	1	0
Pars Distalis, Carcinoma (24) IN 105-105	2	19	31	19
FA 100	1	0	1	0
FA 100	2	36	42	24
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	2	0
KIDNEY (1620) IN 81-104	1	1	1	0
Tubular Adenoma (25) IN 81-104	2	46	50	29
Spontaneous tumor pct: 1% in ctrl. - Total	-	1	1	0
KIDNEY (1620) IN 81-104	1	0	1	0
Tubular Carcinoma (28) IN 81-104	2	47	50	29
IN 105-105	1	1	0	0
IN 105-105	2	18	32	19
Spontaneous tumor pct: 1% in ctrl. - Total	-	1	1	0
KIDNEY (1620) IN INTERIM	1	1	0	0
Liposarcoma (29) IN INTERIM	2	9	0	0
Spontaneous tumor pct: 1% in ctrl. - Total	-	1	0	0
STOMACH (1650) FA 83	1	0	1	0

0.632 0.456 0.799

0.864 0.748 0.945

0.899 0.791 0.960

N/A N/A N/A

0.632 0.425 0.871

Leiomyosarcoma	(31)	FA 83	2	72	79	44	
Spontaneous tumor pct: <= 1% in ctrl.	-	-	-	0	1	0	
STOMACH	(1650)	IN 105-105	1	0	0	1	0.271 0.087 0.500
Nonglandular, Squamous Ce	(32)	IN 105-105	2	19	32	18	
Spontaneous tumor pct: <= 1% in ctrl.	-	-	-	0	0	1	
PANCREAS	(1670)	IN 81-104	1	3	1	0	0.788 0.725 0.845
Islet Cell Adenoma	(33)	IN 81-104	2	44	50	29	
		IN 105-105	1	2	2	3	
		IN 105-105	2	17	30	16	
Spontaneous tumor pct: 5% in ctrl.	-	-	-	5	3	3	
PANCREAS	(1670)	IN 81-104	1	1	0	0	1.000 0.870 0.992
Acinar Cell Adenoma	(34)	IN 81-104	2	46	51	29	
Spontaneous tumor pct: 1% in ctrl.	-	-	-	1	0	0	
LYMPH NODE, MESENTERIC	(1680)	IN 51-80	1	1	0	0	0.596 0.454 0.738
Hemangioma	(37)	IN 51-80	2	30	36	30	
		IN 81-104	1	0	1	0	
		IN 81-104	2	47	50	29	
		IN 105-105	1	0	0	1	
		IN 105-105	2	19	31	18	
Spontaneous tumor pct: 1% in ctrl.	-	-	-	1	1	1	
SKIN	(1740)	FA 90	1	0	0	1	0.228 0.066 0.426
Schwannoma, Malignant	(40)	FA 90	2	60	65	36	
Spontaneous tumor pct: <= 1% in ctrl.	-	-	-	0	0	1	
SKIN	(1740)	IN 105-105	1	1	0	0	1.000 0.912 0.996
Keratoacanthoma	(42)	IN 105-105	2	18	32	19	
Spontaneous tumor pct: 1% in ctrl.	-	-	-	1	0	0	
SKIN	(1740)	IN 81-104	1	0	0	1	0.853 0.750 0.927
Fibroma	(43)	IN 81-104	2	45	49	28	
		IN 105-105	1	2	0	0	
		IN 105-105	2	17	32	19	
Spontaneous tumor pct: 2% in ctrl.	-	-	-	2	0	1	
SKIN	(1740)	IN 81-104	1	1	0	0	1.000 0.872 0.992
Amelanotic Melanoma, Ben	(44)	IN 81-104	2	44	49	29	
Spontaneous tumor pct: 1% in ctrl.	-	-	-	1	0	0	
SKIN	(1740)	FA 69	1	1	0	0	1.000 0.948 0.994
Sarcoma, NOS	(46)	FA 69	2	88	104	62	
		FA 84	1	1	0	0	
		FA 84	2	69	75	44	
Spontaneous tumor pct: 2% in ctrl.	-	-	-	2	0	0	
SKIN	(1740)	IN 51-80	1	0	1	0	0.300 0.183 0.435
Fibrosarcoma	(47)	IN 51-80	2	31	34	29	
		FA 61	1	0	1	0	
		FA 61	2	97	107	71	
		FA 64	1	0	0	1	
		FA 64	2	92	106	64	
Spontaneous tumor pct: <= 1% in ctrl.	-	-	-	0	2	1	
MAMMARY GLAND	(1750)	IN 51-80	1	4	3	3	0.483 0.457 0.511
Fibroadenoma	(53)	IN 51-80	2	21	25	25	
		IN 81-104	1	8	19	5	
		IN 81-104	2	27	16	14	
		IN 105-105	1	14	24	12	
		IN 105-105	2	5	8	7	
		IN INTERIM	1	5	0	0	
		IN INTERIM	2	5	0	0	
		FA 56	1	0	1	0	
		FA 56	2	104	115	76	
		FA 58	1	1	0	0	
		FA 58	2	102	114	75	
		FA 59	1	1	0	0	
		FA 59	2	101	113	75	
		FA 60	1	1	0	1	
		FA 60	2	100	112	71	
		FA 71	1	0	1	0	
		FA 71	2	86	103	60	
		FA 72	1	1	2	0	
		FA 72	2	84	100	58	
		FA 74	1	0	2	0	
		FA 74	2	80	94	55	
		FA 75	1	1	0	0	
		FA 75	2	78	92	54	
		FA 76	1	0	1	0	
		FA 76	2	78	89	54	
		FA 77	1	1	0	0	
		FA 77	2	77	89	51	
		FA 79	1	0	1	0	
		FA 79	2	76	84	49	
		FA 80	1	0	0	1	
		FA 80	2	76	83	48	
		FA 81	1	1	1	1	
		FA 81	2	74	81	47	
		FA 85	1	0	1	0	
		FA 85	2	69	74	43	
		FA 86	1	0	1	0	
		FA 86	2	65	72	42	
		FA 87	0	0	1	0	
		FA 87	2	65	69	41	
		FA 88	1	0	1	1	
		FA 88	2	63	67	39	
		FA 89	1	1	0	0	
		FA 89	2	61	66	39	
		FA 91	1	0	0	2	
		FA 91	2	61	65	34	
		FA 92	1	1	0	0	
		FA 92	2	56	63	33	
		FA 93	1	0	1	0	
		FA 93	2	52	62	31	
		FA 94	1	1	1	0	
		FA 94	2	49	60	29	
		FA 95	1	1	2	1	

		FA 95	2	48 55 27	
		FA 97	1	2 1 1	
		FA 98	2	40 50 26	
		FA 98	1	0 1 0	
		FA 98	2	40 49 26	
		FA 99	1	0 3 1	
		FA 99	2	38 44 25	
		FA 100	1	1 1 1	
		FA 100	2	35 42 23	
		FA 101	1	1 0 0	
		FA 101	2	33 39 23	
		FA 102	1	1 0 1	
		FA 102	2	31 37 22	
		FA 103	1	1 0 0	
		FA 103	2	30 35 22	
		FA 104	1	0 0 1	
		FA 104	2	30 35 19	
		- Total	-	48 69 32	
Spontaneous tumor pct: 48% in ctrl.					
MAMMARY GLAND	(1750	) IN 81-104	1	1 2 0	0.460 0.365 0.564
Adenoma	(54	) IN 81-104	2	45 47 29	
		IN 105-105	1	0 1 1	
		IN 105-105	2	19 31 18	
		FA 75	1	0 1 0	
		FA 75	2	79 91 54	
		FA 95	1	0 1 0	
		FA 95	2	49 56 28	
		- Total	-	1 5 1	
Spontaneous tumor pct: 1% in ctrl.					
MAMMARY GLAND	(1750	) IN 51-80	1	3 1 1	0.892 0.877 0.905
Carcinoma	(55	) IN 51-80	2	20 21 27	
		IN 81-104	1	5 4 1	
		IN 81-104	2	32 39 20	
		IN 105-105	1	9 9 8	
		IN 105-105	2	10 23 11	
		IN INTERIM	1	5 0 0	
		IN INTERIM	2	5 0 0	
		FA 36	1	1 0 0	
		FA 36	2	106120 80	
		FA 48	1	0 1 0	
		FA 48	2	106118 78	
		FA 52	1	0 1 0	
		FA 52	2	106117 77	
		FA 58	1	0 1 0	
		FA 58	2	103113 75	
		FA 61	1	0 1 1	
		FA 61	2	98108 70	
		FA 62	1	0 1 0	
		FA 62	2	97107 68	
		FA 66	1	2 0 0	
		FA 66	2	91106 63	
		FA 70	1	1 0 0	
		FA 70	2	86105 61	
		FA 71	1	0 1 0	
		FA 71	2	86103 60	
		FA 72	1	2 2 0	
		FA 72	2	83100 58	
		FA 73	1	0 1 0	
		FA 73	2	81 98 56	
		FA 74	1	0 4 0	
		FA 74	2	80 92 55	
		FA 75	1	1 1 0	
		FA 75	2	78 91 54	
		FA 76	1	0 1 1	
		FA 76	2	78 89 53	
		FA 77	1	1 0 0	
		FA 77	2	77 89 51	
		FA 78	1	1 0 0	
		FA 78	2	76 87 50	
		FA 81	1	1 0 0	
		FA 81	2	74 82 48	
		FA 85	1	1 0 0	
		FA 85	2	68 75 43	
		FA 87	1	0 0 1	
		FA 87	2	65 70 40	
		FA 88	1	0 0 1	
		FA 88	2	63 68 39	
		FA 91	1	0 0 1	
		FA 91	2	61 65 35	
		FA 92	1	1 0 0	
		FA 92	2	56 63 33	
		FA 93	1	0 0 1	
		FA 93	2	52 63 30	
		FA 94	1	0 1 0	
		FA 94	2	50 60 29	
		FA 95	1	2 0 1	
		FA 95	2	47 57 27	
		FA 96	1	1 0 0	
		FA 96	2	44 52 27	
		FA 98	1	0 1 0	
		FA 98	2	40 49 26	
		FA 99	1	0 3 1	
		FA 99	2	38 44 25	
		FA 100	1	1 1 0	
		FA 100	2	35 42 24	
		FA 101	1	1 1 0	
		FA 101	2	33 38 23	
		FA 102	1	0 0 1	
		FA 102	2	32 37 22	
		FA 103	1	1 0 0	
		FA 103	2	30 35 22	
		FA 104	1	0 0 1	
		FA 104	2	30 35 19	
		- Total	-	40 36 20	
Spontaneous tumor pct: 40% in ctrl.					
SKELETAL MUSCLE	(1770	) FA 41	1	0 1 0	0.651 0.453 0.880
Sarcoma, NOS	(58	) FA 41	2	107120 79	
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0 1 0	
THYROID	(1780	) IN 51-80	1	1 1 1	0.309 0.242 0.383

C-Cell Adenoma	(60)	IN 51-80	2	30	35	29	
		IN 81-104	1	2	2	1	
		IN 81-104	2	45	49	28	
		IN 105-105	1	0	1	2	
		IN 105-105	2	19	31	17	
		IN INTERIM	1	1	0	0	
		IN INTERIM	2	9	0	0	
Spontaneous tumor pct: 4%	in ctrl.	- Total	-	4	4	4	
THYROID	(1780)	IN 51-80	1	1	0	0	0.881 0.779 0.953
Follicular Cell Adenoma	(61)	IN 51-80	2	30	36	30	
		IN 81-104	1	0	1	0	
		IN 81-104	2	47	50	29	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	1	0	
THYROID	(1780)	IN 81-104	1	0	0	1	0.566 0.394 0.749
Follicular Cell Carcinoma	(62)	IN 81-104	2	46	51	28	
		FA 93	1	1	0	0	
		FA 93	2	52	63	31	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	0	1	
THYROID	(1780)	IN 81-104	1	0	1	0	0.868 0.749 0.947
C-Cell Carcinoma	(63)	IN 81-104	2	46	50	29	
		FA 93	1	1	0	0	
		FA 93	2	52	63	31	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	1	0	
URINARY BLADDER	(1940)	IN 105-105	1	0	1	0	0.728 0.500 0.912
Transitional Epithelium,	(71)	IN 105-105	2	19	31	19	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	
OVARY	(1950)	IN 81-104	1	0	1	0	0.275 0.140 0.446
Granulosa Cell Tumor, Ben	(72)	IN 81-104	2	47	50	29	
		IN 105-105	1	0	0	1	
		IN 105-105	2	19	32	18	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	1	
OVARY	(1950)	IN 105-105	1	0	0	1	0.271 0.087 0.500
Sertoli Cell Tumor, Benig	(73)	IN 105-105	2	19	32	18	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	1	
OVARY	(1950)	IN 105-105	1	0	1	0	0.728 0.500 0.912
Luteoma, Benign	(74)	IN 105-105	2	19	31	19	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	
OVARY	(1950)	IN 105-105	1	0	1	0	0.728 0.500 0.912
Tubulostromal Adenoma	(75)	IN 105-105	2	19	31	19	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	
UTERUS	(1960)	FA 101	1	1	0	0	1.000 0.877 0.993
Schwannoma, Malignant	(77)	FA 101	2	33	39	23	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	0	0	
UTERUS	(1960)	IN 81-104	1	1	0	0	1.000 0.870 0.992
Squamous Papilloma	(78)	IN 81-104	2	46	51	29	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	0	0	
UTERUS	(1960)	IN 81-104	1	1	0	0	0.899 0.791 0.960
Granular Cell Tumor, Beni	(79)	IN 81-104	2	46	51	29	
		IN 105-105	1	0	1	0	
		IN 105-105	2	19	31	19	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	1	0	
UTERUS	(1960)	IN 81-104	1	0	1	1	0.552 0.424 0.684
Leiomyoma	(80)	IN 81-104	2	47	50	28	
		IN 105-105	1	1	1	0	
		IN 105-105	2	18	31	19	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	2	1	
UTERUS	(1960)	IN 51-80	1	0	2	2	0.750 0.699 0.798
Endometrial Stromal Polyp	(81)	IN 51-80	2	31	34	28	
		IN 81-104	1	4	4	1	
		IN 81-104	2	43	47	28	
		IN 105-105	1	3	2	1	
		IN 105-105	2	16	30	18	
		IN INTERIM	1	1	0	0	
		IN INTERIM	2	9	0	0	
Spontaneous tumor pct: 8%	in ctrl.	- Total	-	8	8	4	
UTERUS	(1960)	IN 105-105	1	1	0	0	1.000 0.912 0.996
Endometrial Carcinoma	(82)	IN 105-105	2	18	32	19	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	0	0	
UTERUS	(1960)	FA 61	1	1	0	0	1.000 0.989 0.998
Endometrial Stromal Sarco	(83)	FA 61	2	98	110	71	
		FA 63	1	1	0	0	
		FA 63	2	95	108	66	
		FA 91	1	1	0	0	
		FA 91	2	61	65	36	
		FA 97	1	1	0	0	
		FA 97	2	41	51	27	
Spontaneous tumor pct: 4%	in ctrl.	- Total	-	4	0	0	
CERVIX	(1970)	IN 51-80	1	0	1	0	0.680 0.494 0.894
Leiomyoma	(84)	IN 51-80	2	31	35	30	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	
CERVIX	(1970)	IN 105-105	1	1	1	0	0.929 0.833 0.973
Stromal Polyp	(85)	IN 105-105	2	18	31	19	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	1	0	
VAGINA	(1980)	FA 99	1	0	0	1	0.234 0.070 0.442
Schwannoma, Malignant	(86)	FA 99	2	38	47	25	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	1	
VAGINA	(1980)	IN 81-104	1	0	1	0	0.603 0.456 0.748
Granular Cell Tumor, Beni	(87)	IN 81-104	2	47	50	29	
		IN 105-105	1	1	0	1	
		IN 105-105	2	18	32	18	
Spontaneous tumor pct: 1%	in ctrl.	- Total	-	1	1	1	

VAGINA	(1980	)	IN 81-104	1	0	1	0	0.629	0.426	0.870
Leiomyoma	(88	)	IN 81-104	2	47	50	29			
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0			
VAGINA	(1980	)	IN 105-105	1	1	0	0	1.000	0.912	0.996
Stromal Polyp	(89	)	IN 105-105	2	18	32	19			
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0			
SMALL INTESTINE	(5555	)	FA 100	1	0	1	0	0.650	0.438	0.879
Carcinoma	(94	)	FA 100	2	36	42	24			
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0			
SMALL INTESTINE	(5555	)	IN 81-104	1	1	0	0	1.000	0.870	0.992
Leiomyoma	(95	)	IN 81-104	2	46	51	29			
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0			
SMALL INTESTINE	(5555	)	IN 105-105	1	0	0	1	0.271	0.087	0.500
Leiomyosarcoma	(96	)	IN 105-105	2	19	32	18			
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	0	1			
LARGE INTESTINE	(6666	)	IN 51-80	1	1	0	0	1.000	0.967	0.997
Granular Cell Tumor, Beni	(97	)	IN 51-80	2	30	36	30			
			IN 105-105	1	1	0	0			
			IN 105-105	2	18	32	19			
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	0	0			
LARGE INTESTINE	(6666	)	IN 81-104	1	0	0	1	0.228	0.066	0.426
Leiomyoma	(98	)	IN 81-104	2	47	51	28			
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	0	1			
LARGE INTESTINE	(6666	)	IN 105-105	1	0	1	0	0.728	0.500	0.912
Leiomyosarcoma	(99	)	IN 105-105	2	19	31	19			
Spontaneous tumor pct: <= 1%	in ctrl.	-	Total	-	0	1	0			
SYSTEMIC NEOPLASMS	(7777	)	IN 81-104	1	0	1	0	0.645	0.549	0.745
Histiocytic Sarcoma	(100	)	IN 81-104	2	46	48	29			
			FA 76	1	0	0	1			
			FA 76	2	79	91	53			
			FA 90	1	0	1	0			
			FA 90	2	62	65	37			
			FA 96	1	1	0	0			
			FA 96	2	44	52	27			
			FA 102	1	0	1	0			
			FA 102	2	32	36	23			
			FA 105	1	1	0	0			
			FA 105	2	28	32	19			
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	3	1			
SYSTEMIC NEOPLASMS	(7777	)	IN 81-104	1	0	1	0	0.664	0.574	0.754
Lymphoma	(101	)	IN 81-104	2	46	49	29			
			IN 105-105	1	0	1	1			
			IN 105-105	2	19	30	18			
			FA 28	1	1	0	0			
			FA 28	2	108	121	83			
			FA 95	1	1	0	0			
			FA 95	2	49	57	28			
			FA 100	1	0	1	0			
			FA 100	2	36	42	24			
			FA 105	1	0	1	0			
			FA 105	2	29	31	19			
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	4	1			
SYSTEMIC NEOPLASMS	(7777	)	IN 105-105	1	1	0	0	1.000	0.912	0.996
Mononuclear Cell Leukemia	(102	)	IN 105-105	2	18	32	19			
Spontaneous tumor pct: 1%	in ctrl.	-	Total	-	1	0	0			

APPEARS THIS WAY
ON ORIGINAL

Table 9

Number of Animals
Species: Mouse
Sex: Male

	Treatment Group				
	CTRL	LOW	MED	HIGH	Total
	N	N	N	N	N
Week					
0-50	6	7	17	30	60
51-80	33	19	33	37	122
81-104	31	45	28	17	121
105-105	30	29	22	16	97
Total	100	100	100	100	400

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Table 10

Number of Animals
Species: Mouse
Sex: Female

	Treatment Group				
	CTRL	LOW	MED	HIGH	Total
	N	N	N	N	N
Week					
0-50	3	6	15	47	71
51-80	17	24	33	24	98
81-101	34	40	29	16	119
102-103	46	30	23	13	112
Total	100	100	100	100	400

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ON ORIGINAL

Table 11

Analysis of Mortality
Species: Mouse
Sex: Male

Week	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
0-50	6	100	6.0	7	100	7.0	17	100	17.0	30	100	30.0
51-80	33	94	39.0	19	93	26.0	33	83	50.0	37	70	67.0
81-104	31	61	70.0	45	74	71.0	28	50	78.0	17	33	84.0
105- 105	30	100	30.0	29	100	29.0	22	100	22.0	16	100	16.0

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ON ORIGINAL

Table 12

Analysis of Mortality
Species: Mouse
Sex: Female

Week	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
0-50	3	100	3.0	6	100	6.0	15	100	15.0	47	100	47.0
51-80	17	97	20.0	24	94	30.0	33	85	48.0	24	53	71.0
81-101	34	80	54.0	40	70	70.0	29	52	77.0	16	29	87.0
102- 103	46	100	46.0	30	100	30.0	23	100	23.0	13	100	13.0

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ON ORIGINAL

Table 13

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	25.66	0.0000
	Depart from Trend	2.78	0.2492
	Homogeneity	28.44	0.0000
Kruskal-wallis	Dose-Mortality Trend	42.56	0.0000
	Depart from Trend	5.58	0.0615
	Homogeneity	48.14	0.0000

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Table 14

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	62.90	0.0000
	Depart from Trend	1.10	0.5759
	Homogeneity	64.00	0.0000
Kruskal-Wallis	Dose-Mortality Trend	83.89	0.0000
	Depart from Trend	2.48	0.2887
	Homogeneity	86.37	0.0000

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Table 15

Analysis of Carcinogenic Potential in Male Mouse
 Test of Dose-Response (Tumor) Positive Linear Trend
 Dose Levels Included: CTRL1 LOW MED HIGH (0, 6.25, 12.5, 25)

Study No. 97091
 Run Date & Time: June 28, 2001 (17:31)
 Source: C:\N21-341\MICE\MALE\XAnimalX.txt
 Note: Dose Levels Included: CTRL1 LOW MED HIGH (0, 6.25, 12.5, 25)
 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 TABLES	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
ADRENAL(S)	(1)	IN 81-104	1	1 1 0 1	
#B - ADENOMA, SUBCAPSULAR	(1)	IN 81-104	2	30 44 28 16	
		IN 105-105	1	2 1 0 0	
		IN 105-105	2	27 28 22 16	
Spontaneous tumor pct: 3%		- Total	-	3 2 0 1	
ADRENAL(S)	(1)	IN 105-105	1	0 1 0 0	0.697 0.623 0.645
#M - CORTICAL CARCINOMA	(4)	IN 105-105	2	29 28 22 16	
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0	
ADRENAL(S)	(1)	IN 81-104	1	1 0 0 0	0.336 0.263 0.277
#B - CORTICAL ADENOMA	(5)	IN 81-104	2	30 45 28 17	
		IN 105-105	1	0 0 0 1	
		IN 105-105	2	29 29 22 15	
Spontaneous tumor pct: <= 1%		- Total	-	1 0 0 1	
EPIDIDYMIS(IDES)	(12)	IN 105-105	1	0 0 1 0	0.391 0.332 0.354
#B - LEIOMYOMA	(6)	IN 105-105	2	30 29 21 16	
Spontaneous tumor pct: <= 1%		- Total	-	0 0 1 0	
KIDNEY(S)	(20)	IN 81-104	1	1 0 0 0	0.976 0.920 0.925
#B - TUBULAR ADENOMA	(9)	IN 81-104	2	30 45 28 17	
		IN 105-105	1	1 1 0 0	
		IN 105-105	2	29 28 22 16	
Spontaneous tumor pct: 2%		- Total	-	2 1 0 0	
GROSS CONDITION	(201)	IN 51-80	1	0 1 0 0	0.729 0.719 0.736
#M - HEMANGIOSARCOMA, FOO	(53)	IN 51-80	2	33 18 33 37	
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0	
GROSS CONDITION	(201)	FA 94	1	0 1 0 0	0.684 0.617 0.639
#M - CARCINOMA, NOS	(54)	FA 94	2	47 43 33 25	
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0	
SUBCUTIS	(202)	FA 34	1	0 1 0 0	0.736 0.673 0.693
#M - HEMANGIOSARCOMA	(56)	FA 34	2	97 98 90 82	
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0	
SUBCUTIS	(202)	FA 104	1	0 0 0 1	0.171 0.030 0.035
#M - FIBROSARCOMA	(57)	FA 104	2	31 29 22 16	
Spontaneous tumor pct: <= 1%		- Total	-	0 0 0 1	
SUBCUTIS	(202)	IN 81-104	1	1 0 0 0	1.000 0.865 0.878
#B - FIBROMA	(58)	IN 81-104	2	30 45 28 17	
Spontaneous tumor pct: <= 1%		- Total	-	1 0 0 0	
LIVER	(21)	IN 0-50	1	0 0 1 0	0.388 0.366 0.370
#B - HEPATOCELLULAR ADENO	(10)	IN 0-50	2	6 7 15 29	
		IN 51-80	1	0 1 2 0	
		IN 51-80	2	33 18 31 37	
		IN 81-104	1	2 2 2 2	
		IN 81-104	2	29 43 26 15	
		IN 105-105	1	7 7 6 4	
		IN 105-105	2	23 22 16 12	
Spontaneous tumor pct: 9%		- Total	-	9 10 11 6	
LIVER	(21)	IN 105-105	1	0 1 0 0	0.782 0.745 0.753
#M - HEMANGIOSARCOMA	(11)	IN 105-105	2	30 28 22 16	
		FA 69	1	0 1 0 0	
		FA 69	2	79 85 70 40	
		FA 84	1	0 1 0 0	
		FA 84	2	59 67 45 30	
		FA 95	1	1 0 0 0	
		FA 95	2	46 43 28 23	
		FA 99	1	0 0 1 0	
		FA 99	2	35 38 25 20	
Spontaneous tumor pct: <= 1%		- Total	-	1 3 1 0	
LIVER	(21)	IN 51-80	1	0 1 0 2	0.017 0.012 0.013
#M - HEPATOCELLULAR CARCI	(12)	IN 51-80	2	30 17 33 35	
		IN 81-104	1	0 0 0 2	
		IN 81-104	2	30 42 26 13	
		IN 105-105	1	2 6 2 5	
		IN 105-105	2	28 23 20 11	
		FA 68	1	1 0 0 0	
		FA 68	2	80 88 70 43	
		FA 69	1	1 0 0 0	
		FA 69	2	78 86 70 40	
		FA 74	1	1 0 0 0	
		FA 74	2	72 81 62 35	
		FA 78	1	0 1 0 0	
		FA 78	2	66 78 52 35	

	FA 84	1	0	1	0	0	
	FA 84	2	59	67	45	30	
	FA 87	1	0	0	1	0	
	FA 87	2	59	59	39	29	
	FA 90	1	0	0	0	1	
	FA 90	2	54	54	35	26	
	FA 91	1	0	1	0	0	
	FA 91	2	52	51	35	25	
	FA 92	1	0	0	1	0	
	FA 92	2	50	49	34	25	
	FA 93	1	1	0	0	0	
	FA 93	2	49	47	33	25	
	FA 101	1	0	0	0	1	
	FA 101	2	34	34	23	18	
	FA 102	1	0	1	0	0	
	FA 102	2	33	32	23	17	
Spontaneous tumor pct: 6%	in ctrl.	- Total	-	6	11	4	11
LIVER	(21)	IN 81-104	1	0	1	0	0
#B - HEMANGIOMA	(13)	IN 81-104	2	31	44	28	17
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	0
LIVER	(21)	IN 105-105	1	0	1	0	0
#M - HEPATOBLASTOMA	(14)	IN 105-105	2	30	28	22	16
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	0
HEMATOPOIETIC SYSTEM	(213)	IN 105-105	1	3	0	1	1
#M - LYMPHOMA	(60)	IN 105-105	2	27	29	21	15
	FA 11	1	0	0	0	1	
	FA 11	2	100	100	100	97	
	FA 24	1	1	0	0	0	
	FA 24	2	98	99	97	89	
	FA 33	1	0	0	0	1	
	FA 33	2	97	99	91	82	
	FA 48	1	1	0	0	1	
	FA 48	2	94	94	85	72	
	FA 53	1	1	0	0	0	
	FA 53	2	93	93	81	67	
	FA 59	1	0	1	0	0	
	FA 59	2	91	92	75	54	
	FA 72	1	0	1	0	0	
	FA 72	2	75	82	66	39	
	FA 75	1	0	0	1	0	
	FA 75	2	70	81	58	35	
	FA 83	1	0	0	1	0	
	FA 83	2	59	68	46	32	
	FA 84	1	0	1	0	0	
	FA 84	2	59	67	45	30	
	FA 90	1	0	1	0	0	
	FA 90	2	54	53	35	27	
	FA 95	1	0	0	1	0	
	FA 95	2	47	43	27	23	
	FA 97	1	0	1	0	0	
	FA 97	2	39	39	26	21	
	FA 98	1	1	0	0	0	
	FA 98	2	36	38	26	21	
	FA 102	1	0	1	0	0	
	FA 102	2	33	32	23	17	
Spontaneous tumor pct: 7%	in ctrl.	- Total	-	7	6	4	4
HEMATOPOIETIC SYSTEM	(213)	FA 72	1	1	0	0	0
#M - LEUKEMIA, GRANULOCYT	(61)	FA 72	2	74	83	66	39
	FA 74	1	0	0	1	0	
	FA 74	2	73	81	61	35	
	FA 82	1	0	1	0	0	
	FA 82	2	59	71	49	33	
	FA 89	1	0	0	1	0	
	FA 89	2	57	56	37	28	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	1	2	0
HEMATOPOIETIC SYSTEM	(213)	IN 105-105	1	0	0	1	0
#M - HISTIOCYTIC SARCOMA	(62)	IN 105-105	2	30	29	21	16
	FA 63	1	0	0	1	0	
	FA 63	2	89	91	73	50	
	FA 91	1	1	0	0	0	
	FA 91	2	51	52	35	25	
	FA 95	1	1	0	0	0	
	FA 95	2	46	43	28	23	
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2	0	2	0
LUNG(S)	(23)	IN 51-80	1	1	0	0	0
#M - BRONCHIOLO-ALVEOLAR	(15)	IN 51-80	2	29	18	32	37
	IN 81-104	1	1	0	0	0	
	IN 81-104	2	24	41	25	16	
	IN 105-105	1	6	3	4	6	
	IN 105-105	2	24	26	18	10	
	FA 59	1	0	0	1	0	
	FA 59	2	91	93	74	54	
	FA 65	1	0	1	0	0	
	FA 65	2	83	89	72	49	
	FA 68	1	1	0	0	0	
	FA 68	2	80	88	70	43	
	FA 74	1	1	0	0	0	
	FA 74	2	72	81	62	35	
	FA 76	1	1	0	0	0	
	FA 76	2	68	81	58	35	
	FA 89	1	0	1	1	0	
	FA 89	2	57	55	37	28	
	FA 93	1	0	1	0	0	
	FA 93	2	50	46	33	25	
	FA 94	1	0	0	1	0	
	FA 94	2	47	44	32	25	
	FA 95	1	0	1	0	1	
	FA 95	2	47	42	28	22	
	FA 96	1	2	0	0	0	
	FA 96	2	40	42	27	22	
	FA 97	1	1	0	0	0	
	FA 97	2	38	40	26	21	
	FA 99	1	0	1	0	0	
	FA 99	2	35	37	26	20	

0.743 0.623 0.647

0.690 0.619 0.641

0.577 0.556 0.561

0.625 0.585 0.597

0.756 0.718 0.728

0.738 0.722 0.725

	FA 100	1	1	0	0	0	
	FA 100	2	34	37	25	20	
	FA 101	1	1	0	0	0	
	FA 101	2	33	34	23	19	
	FA 103	1	0	0	1	0	
	FA 103	2	32	31	22	17	
	FA 104	1	1	0	0	0	
	FA 104	2	30	29	22	17	
Spontaneous tumor pct: 17%	in ctrl.	- Total	17	8	8	7	
LUNG(S)	(23)						
#B - BRONCHOALVEOLAR ADEN	(16)						
	IN 0-50	1	0	0	1	1	0.911 0.900 0.902
	IN 0-50	2	6	7	16	29	
	IN 51-80	1	5	1	4	3	
	IN 51-80	2	28	18	29	34	
	IN 81-104	1	7	6	2	1	
	IN 81-104	2	24	39	26	16	
	IN 105-105	1	7	2	1	4	
	IN 105-105	2	23	27	21	12	
Spontaneous tumor pct: 19%	in ctrl.	- Total	19	9	8	9	
PANCREAS	(30)						
#B - ISLET CELL ADENOMA	(24)						
	IN 81-104	1	0	0	1	0	0.893 0.833 0.842
	IN 81-104	2	31	45	27	17	
	IN 105-105	1	2	0	0	0	
	IN 105-105	2	28	29	22	16	
Spontaneous tumor pct: 2%	in ctrl.	- Total	2	0	1	0	
PARATHYROID(S)	(31)						
#B - ADENOMA	(25)						
	IN 105-105	1	0	1	0	0	0.691 0.615 0.637
	IN 105-105	2	29	28	21	15	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	1	0	0	
PITUITARY	(35)						
#B - ADENOMA, PARS DISTAL	(26)						
	IN 81-104	1	0	0	1	0	0.489 0.460 0.477
	IN 81-104	2	30	45	26	17	
	IN 105-105	1	0	1	0	0	
	IN 105-105	2	30	28	22	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	1	1	0	
PITUITARY	(35)						
#M - CARCINOMA, PARS DIST	(27)						
	IN 105-105	1	0	1	0	0	0.690 0.619 0.641
	IN 105-105	2	30	28	22	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	1	0	0	
SALIVARY GLAND	(38)						
#M - MALIGNANT FIBROUS HI	(29)						
	IN 105-105	1	0	0	1	0	0.391 0.332 0.354
	IN 105-105	2	30	29	21	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	1	0	
SKELETAL MUSCLE	(40)						
#B - HEMANGIOMA	(30)						
	IN 51-80	1	0	0	1	0	0.573 0.477 0.497
	IN 51-80	2	33	19	32	37	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	1	0	
SKIN	(41)						
#M - SQUAMOUS CELL CARCIN	(34)						
	FA 58	1	0	0	0	1	0.029 0.004 0.004
	FA 58	2	91	93	77	54	
	FA 104	1	0	0	0	1	
	FA 104	2	31	29	22	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	0	2	(Exact P<0.050)
SPLEEN	(43)						
#M - HEMANGIOSARCOMA	(35)						
	IN 81-104	1	0	1	0	1	0.276 0.211 0.222
	IN 81-104	2	31	44	28	16	
	IN 105-105	1	0	1	0	0	
	IN 105-105	2	30	28	22	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	2	0	1	
TESTIS(ES)	(46)						
#B - INTERSTITIAL CELL TU	(36)						
	IN 81-104	1	1	0	0	0	0.998 0.987 0.988
	IN 81-104	2	29	45	28	17	
	IN 105-105	1	4	0	1	0	
	IN 105-105	2	26	29	21	16	
	FA 102	1	1	0	0	0	
	FA 102	2	32	33	23	17	
Spontaneous tumor pct: 6%	in ctrl.	- Total	6	0	1	0	
LARGE INTESTINE	(666)						
#M - ADENOCARCINOMA, MUCI	(63)						
	IN 81-104	1	0	0	1	0	0.371 0.316 0.339
	IN 81-104	2	31	45	27	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	0	0	1	0	
HARDERIAN GLAND	(70)						
#B - ADENOMA	(50)						
	IN 51-80	1	1	0	1	0	0.908 0.890 0.892
	IN 51-80	2	32	19	32	37	
	IN 81-104	1	2	3	2	1	
	IN 81-104	2	29	42	26	16	
	IN 105-105	1	6	1	2	1	
	IN 105-105	2	24	28	20	15	
Spontaneous tumor pct: 9%	in ctrl.	- Total	9	4	5	2	
HARDERIAN GLAND	(70)						
#M - ADENOCARCINOMA	(51)						
	IN 51-80	1	0	0	1	0	0.613 0.579 0.587
	IN 51-80	2	33	19	32	37	
	IN 81-104	1	0	1	0	1	
	IN 81-104	2	31	44	28	16	
	IN 105-105	1	3	0	2	0	
	IN 105-105	2	27	29	20	16	
Spontaneous tumor pct: 3%	in ctrl.	- Total	3	1	3	1	

Table 16

Analysis of Carcinogenic Potential in Female Mouse
 Test of Dose-Response (Tumor) Positive Linear Trend
 Dose Levels Included: CTRL LOW MED HIGH (0, 12.5, 25, 50)

Study No. 97091
 Run Date & Time: June 28, 2001 (17:52)
 Source: C:\N21-341\MICE\FEMALE\XANIMALX.txt

Note: Dose Levels Included: CTRL LOW MED HIGH (0 12.5 25 50)
 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 TABLES	EXACT PROB	ASYMP PROB	ASYMP /CONT CORR	PROB OBSERVED
ADRENAL(S)	(1)	IN 81-101	1	1 0 1 0	0.117	0.085	0.087	
#B - ADENOMA, SUBCAPSULAR	(1)	IN 81-101	2	33 40 28 16				
		IN 102-103	1	1 1 1 2				
		IN 102-103	2	45 29 22 11				
Spontaneous tumor pct: 2%		- Total	-	2 1 2 2				
ADRENAL(S)	(1)	IN 51-80	1	1 0 0 0	0.859	0.814	0.819	
#B - PHEOCHROMOCYTOMA	(2)	IN 51-80	2	16 24 33 24				
		IN 102-103	1	1 1 1 0				
		IN 102-103	2	45 29 22 13				
Spontaneous tumor pct: 2%		- Total	-	2 1 1 0				
ADRENAL(S)	(1)	IN 81-101	1	0 1 0 0	0.714	0.612	0.624	
#M - PHEOCHROMOCYTOMA	(3)	IN 81-101	2	34 39 29 16				
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0				
GALL BLADDER	(16)	IN 102-103	1	1 0 0 0	1.000	0.813	0.821	
#B - ADENOMA	(7)	IN 102-103	2	45 29 23 13				
Spontaneous tumor pct: <= 1%		- Total	-	1 0 0 0				
KIDNEY(S)	(20)	FA 84	1	0 0 1 0	0.351	0.277	0.288	
#M - NEPHROBLASTOMA	(8)	FA 84	2	77 65 49 27				
Spontaneous tumor pct: <= 1%		- Total	-	0 0 1 0				
SUBCUTIS	(202)	FA 16	1	0 1 0 0	0.746	0.690	0.700	
#M - MALIGNANT FIBROUS HI	(55)	FA 16	2	100 98 99 97				
Spontaneous tumor pct: <= 1%		- Total	-	0 1 0 0				
SUBCUTIS	(202)	FA 91	1	1 0 0 0	1.000	0.827	0.835	
#M - FIBROSARCOMA	(57)	FA 91	2	63 47 38 21				
Spontaneous tumor pct: <= 1%		- Total	-	1 0 0 0				
MOUTH	(207)	IN 102-103	1	0 0 1 0	0.321	0.251	0.261	
#B - PAPILLOMA	(59)	IN 102-103	2	46 30 22 13				
Spontaneous tumor pct: <= 1%		- Total	-	0 0 1 0				
LIVER	(21)	IN 51-80	1	1 0 1 0	0.728	0.692	0.696	
#B - HEPATOCELLULAR ADENO	(10)	IN 51-80	2	16 24 32 24				
		IN 81-101	1	0 0 1 0				
		IN 81-101	2	34 40 28 16				
		IN 102-103	1	1 2 1 0				
		IN 102-103	2	45 28 22 13				
Spontaneous tumor pct: 2%		- Total	-	2 2 3 0				
LIVER	(21)	IN 51-80	1	0 0 0 1	0.485	0.433	0.439	
#M - HEMANGIOSARCOMA	(11)	IN 51-80	2	17 23 33 23				
		IN 102-103	1	1 1 0 0				
		IN 102-103	2	45 29 23 13				
		FA 74	1	0 1 0 0				
		FA 74	2	84 74 63 39				
Spontaneous tumor pct: <= 1%		- Total	-	1 2 0 1				
LIVER	(21)	IN 81-101	1	0 0 0 1	0.204	0.142	0.147	
#M - HEPATOCELLULAR CARCI	(12)	IN 81-101	2	34 40 29 15				
		IN 102-103	1	1 0 1 0				
		IN 102-103	2	45 30 22 13				
Spontaneous tumor pct: <= 1%		- Total	-	1 0 1 1				
HEMATOPOIETIC SYSTEM	(213)	IN 51-80	1	0 0 1 1	0.143	0.126	0.127	
#M - LYMPHOMA	(60)	IN 51-80	2	17 23 30 22				
		IN 102-103	1	4 3 0 2				
		IN 102-103	2	42 27 23 11				
		FA 29	1	0 0 0 1				
		FA 29	2	100 96 95 78				
		FA 37	1	1 0 0 0				
		FA 37	2	98 96 92 70				
		FA 65	1	0 0 1 0				
		FA 65	2	92 86 76 46				
		FA 71	1	0 1 1 1				
		FA 71	2	89 81 69 40				
		FA 83	1	1 0 0 0				
		FA 83	2	78 65 51 27				
		FA 84	1	1 0 0 0				
		FA 84	2	76 65 50 27				
		FA 87	1	1 1 0 0				
		FA 87	2	72 55 44 24				
		FA 88	1	0 0 1 0				
		FA 88	2	70 54 40 24				
		FA 89	1	0 0 1 1				
		FA 89	2	67 53 38 23				
		FA 92	1	1 0 0 0				
		FA 92	2	60 43 37 18				

		FA 94	1	0	1	1	0	
		FA 94	2	58	41	32	18	
		FA 95	1	0	0	1	0	
		FA 95	2	54	40	31	18	
Spontaneous tumor pct: 9%	in ctrl.	- Total	-	9	6	7	6	
HEMATOPOIETIC SYSTEM (213)		FA 65	1	0	0	0	1	0.109 0.070 0.073
#M - LEUKEMIA, GRANULOCYT (61)		FA 65	2	92	86	77	45	
		FA 74	1	0	0	0	1	
		FA 74	2	84	75	63	38	
		FA 84	1	1	0	0	0	
		FA 84	2	76	65	50	27	
		FA 102	1	0	1	0	0	
		FA 102	2	46	29	23	13	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	1	1	0	2	
HEMATOPOIETIC SYSTEM (213)		IN 102-103	1	1	0	0	0	0.248 0.214 0.217
#M - HISTIOCYTIC SARCOMA (62)		IN 102-103	2	45	30	23	13	
		FA 42	1	0	0	1	0	
		FA 42	2	97	96	90	62	
		FA 77	1	0	0	0	1	
		FA 77	2	83	72	59	32	
		FA 82	1	0	0	0	1	
		FA 82	2	79	68	51	28	
		FA 86	1	0	1	0	0	
		FA 86	2	74	59	46	25	
		FA 88	1	1	0	0	0	
		FA 88	2	69	54	41	24	
		FA 91	1	0	1	0	0	
		FA 91	2	64	46	38	21	
		FA 94	1	0	1	0	0	
		FA 94	2	58	41	33	18	
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2	3	1	2	
LUNG(S) (23)		IN 0-50	1	0	0	1	0	0.351 0.325 0.327
#M - BRONCHIOLO-ALVEOLAR (15)		IN 0-50	2	3	6	14	46	
		IN 51-80	1	0	0	0	1	
		IN 51-80	2	17	24	33	22	
		IN 81-101	1	1	0	0	0	
		IN 81-101	2	32	39	29	14	
		IN 102-103	1	4	3	1	0	
		IN 102-103	2	42	27	22	13	
		FA 74	1	0	0	0	1	
		FA 74	2	84	75	63	38	
		FA 86	1	1	0	0	1	
		FA 86	2	73	60	46	24	
		FA 90	1	0	1	0	0	
		FA 90	2	65	51	38	22	
		FA 101	1	0	0	0	1	
		FA 101	2	46	32	23	13	
Spontaneous tumor pct: 6%	in ctrl.	- Total	-	6	4	2	4	
LUNG(S) (23)		IN 51-80	1	1	2	5	1	0.765 0.749 0.750
#B - BRONCHOALVEOLAR ADEN (16)		IN 51-80	2	16	22	28	23	
		IN 81-101	1	4	7	4	1	
		IN 81-101	2	30	33	25	15	
		IN 102-103	1	6	6	4	1	
		IN 102-103	2	40	24	19	12	
Spontaneous tumor pct: 11%	in ctrl.	- Total	-	11	15	13	3	
MAMMARY GLAND (24)		IN 81-101	1	0	1	0	0	0.362 0.333 0.336
#M - ADENOCARCINOMA (17)		IN 81-101	2	27	38	26	12	
		FA 81	1	1	0	0	0	
		FA 81	2	76	70	51	27	
		FA 90	1	0	1	0	0	
		FA 90	2	64	51	38	21	
		FA 91	1	0	0	0	1	
		FA 91	2	63	47	38	19	
		FA 92	1	0	0	1	0	
		FA 92	2	61	43	36	17	
		FA 95	1	1	0	0	0	
		FA 95	2	53	40	32	17	
		FA 96	1	0	0	1	0	
		FA 96	2	51	39	29	17	
		FA 99	1	1	0	0	1	
		FA 99	2	48	35	27	16	
		FA 100	1	1	0	0	0	
		FA 100	2	46	34	25	16	
Spontaneous tumor pct: 4%	in ctrl.	- Total	-	4	2	2	2	
OVARY(IES) (28)		IN 51-80	1	0	0	0	1	0.253 0.176 0.182
#B - LUTEOMA (18)		IN 51-80	2	17	24	33	23	
		IN 81-101	1	0	1	0	0	
		IN 81-101	2	34	39	29	16	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	0	1	0	1	
OVARY(IES) (28)		IN 51-80	1	0	0	1	0	0.581 0.470 0.482
#B - HEMANGIOMA (19)		IN 51-80	2	17	24	32	24	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	0	0	1	0	
OVARY(IES) (28)		IN 51-80	1	0	1	0	0	0.826 0.742 0.751
#B - TERATOMA (20)		IN 51-80	2	17	23	33	24	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	0	1	0	0	
OVARY(IES) (28)		IN 81-101	1	1	0	1	0	0.803 0.767 0.771
#B - CYSTADENOMA (21)		IN 81-101	2	33	40	28	16	
		IN 102-103	1	2	2	1	0	
		IN 102-103	2	44	28	22	13	
Spontaneous tumor pct: 3%	in ctrl.	- Total	-	3	2	2	0	
OVARY(IES) (28)		FA 91	1	0	1	0	0	0.406 0.381 0.389
#M - GRANULOSA CELL TUMOR (22)		FA 91	2	64	46	38	21	
		FA 99	1	0	0	1	0	
		FA 99	2	49	35	26	17	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	0	1	1	0	
OVARY(IES) (28)		FA 84	1	0	1	0	0	0.648 0.576 0.588
#B - GRANULOSA CELL TUMOR (23)		FA 84	2	77	64	50	27	
Spontaneous tumor pct: <= 1% in ctrl.	- Total	-	-	0	1	0	0	

PANCREAS	(30)	IN 81-101	1	0	1	0	0	0.421	0.394	0.402
#B - ISLET CELL ADENOMA	(24)	IN 81-101	2	33	39	29	16			
		IN 102-103	1	0	0	1	0			
		IN 102-103	2	46	30	22	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	1	0			
PITUITARY	(35)	IN 51-80	1	0	0	1	0	0.422	0.382	0.387
#B - ADENOMA, PARS DISTAL	(26)	IN 51-80	2	17	24	31	24			
		IN 81-101	1	1	0	1	0			
		IN 81-101	2	30	37	28	16			
		IN 102-103	1	1	1	0	1			
		IN 102-103	2	45	29	23	11			
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	1	2	1			
PITUITARY	(35)	IN 102-103	1	1	0	1	0	0.490	0.440	0.447
#M - CARCINOMA, PARS DIST	(27)	IN 102-103	2	45	30	22	12			
		FA 59	1	0	0	1	0			
		FA 59	2	93	86	82	48			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	2	0			
PITUITARY	(35)	IN 81-101	1	0	0	0	1	0.141	0.021	0.023
#B - ADENOMA, PARS INTERM	(28)	IN 81-101	2	31	37	29	15			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	0	0	1			
SKIN	(41)	IN 51-80	1	0	1	0	0	0.822	0.737	0.746
#B - SQUAMOUS PAPILLOMA	(31)	IN 51-80	2	17	23	32	23			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
SKIN	(41)	FA 101	1	0	1	0	0	0.600	0.550	0.563
#M - NEUROFIBROSARCOMA	(32)	FA 101	2	46	31	23	14			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
SKIN	(41)	IN 102-103	1	0	1	0	0	0.589	0.544	0.556
#M - FIBROSARCOMA	(33)	IN 102-103	2	46	29	23	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
SPLEEN	(43)	IN 102-103	1	2	0	0	0	1.000	0.897	0.901
#M - HEMANGIOSARCOMA	(35)	IN 102-103	2	44	30	23	13			
Spontaneous tumor pct: 2% in ctrl.		- Total	-	2	0	0	0			
THYROID(S)	(48)	IN 81-101	1	0	1	0	0	0.714	0.612	0.624
#B - FOLLICULAR ADENOMA/C	(37)	IN 81-101	2	34	39	29	16			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
TONGUE	(49)	IN 81-101	1	1	0	0	0	1.000	0.858	0.865
#M - SQUAMOUS CELL CARCIN	(38)	IN 81-101	2	33	39	29	16			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
URINARY BLADDER	(54)	IN 102-103	1	1	0	0	0	1.000	0.813	0.822
#B - MESENCHYMAL TUMOR	(39)	IN 102-103	2	45	30	23	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
UTERUS	(55)	IN 81-101	1	0	0	1	1	0.149	0.115	0.117
#M - STROMAL SARCOMA	(40)	IN 81-101	2	33	39	28	15			
		IN 102-103	1	0	2	0	0			
		IN 102-103	2	46	28	23	13			
		FA 56	1	0	0	0	1			
		FA 56	2	97	91	84	51			
		FA 90	1	0	1	0	0			
		FA 90	2	65	51	38	22			
		FA 95	1	1	0	0	0			
		FA 95	2	53	40	32	18			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	3	1	2			
UTERUS	(55)	IN 0-50	1	0	0	0	1	0.228	0.207	0.209
#B - MUCOSAL POLYP	(41)	IN 0-50	2	3	6	15	46			
		IN 51-80	1	0	0	1	0			
		IN 51-80	2	17	24	32	24			
		IN 81-101	1	2	5	4	1			
		IN 81-101	2	32	35	24	15			
		IN 102-103	1	3	4	1	2			
		IN 102-103	2	43	26	22	11			
		FA 99	1	0	0	1	0			
		FA 99	2	49	35	26	17			
Spontaneous tumor pct: 5% in ctrl.		- Total	-	5	9	7	4			
UTERUS	(55)	IN 81-101	1	0	1	0	0	0.669	0.630	0.636
#M - LEIOMYOSARCOMA	(42)	IN 81-101	2	33	39	29	16			
		IN 102-103	1	0	1	1	0			
		IN 102-103	2	46	29	22	13			
		FA 94	1	1	0	0	0			
		FA 94	2	57	42	33	18			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	2	1	0			
UTERUS	(55)	IN 81-101	1	0	0	0	1	0.057	0.024	0.025
#B - FIBROMA	(43)	IN 81-101	2	34	40	29	15			
		IN 102-103	1	1	0	0	1			
		IN 102-103	2	45	30	23	12			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	2			
UTERUS	(55)	IN 102-103	1	4	2	0	0	0.978	0.943	0.944
#B - LEIOMYOMA	(44)	IN 102-103	2	42	28	23	13			
Spontaneous tumor pct: 4% in ctrl.		- Total	-	4	2	0	0			
UTERUS	(55)	IN 102-103	1	0	1	0	0	0.589	0.544	0.556
#B - HEMANGIOMA	(45)	IN 102-103	2	46	29	23	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	0	0			
UTERUS	(55)	IN 102-103	1	0	1	1	0	0.371	0.346	0.354
#M - ADENOCARCINOMA/CARCI	(46)	IN 102-103	2	46	29	22	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	0	1	1	0			
UTERUS	(55)	IN 102-103	1	1	0	0	0	1.000	0.813	0.822
#M - SCHWANNOMA	(47)	IN 102-103	2	45	30	23	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			
UTERUS	(55)	IN 102-103	1	1	0	0	0	1.000	0.813	0.822
#M - HEMANGIOSARCOMA	(48)	IN 102-103	2	45	30	23	13			
Spontaneous tumor pct: <= 1% in ctrl.		- Total	-	1	0	0	0			

VAGINA	(56	}	IN 81-101	1	0	0	0	1	0.134	0.018	0.020
#B - LEIOMYOMA	(49	}	IN 81-101	2	34	40	29	15			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	-	0	0	0	1			
HARDERIAN GLAND	(70	}	IN 81-101	1	1	2	2	0	0.201	0.168	0.171
#B - ADENOMA	(50	}	IN 81-101	2	33	38	27	16			
			IN 102-103	1	0	1	2	1			
			IN 102-103	2	46	28	21	12			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	-	1	3	4	1			
GANGLION, GASSERION	(85	}	FA 83	1	1	0	0	0	1.000	0.834	0.842
#M - SCHWANNOMA	(52	}	FA 83	2	78	65	51	27			
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	-	1	0	0	0			

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Table 17

Combined organ and tumor analyses

Analysis of Carcinogenic Potential in Male Rat

Test of Dose-Response (Tumor) Positive Linear Trend

Dose Levels Included: CTRL LOW MED HIGH (0, 2.5, 5.0, 7.5)

Study No. 97095
Run Date & Time: July 3, 2001 (12:55)
Source: C:\N21-341\RAT\MALE\XANIMAX.txt
Note: Dose Levels Included: CTRL LOW MED HIGH (0 2.5 5 7.5)
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 -----TABLES-----	EXACT ASYMP PROB	ASYMP /CONT	PROB CORR
					=P(STAT	.GE.	OBSERVED)

Organ: Liver

Tumor: hepatocellular adenoma + carcinoma

		(1580 C30)	IN 51-80	1	1	0	0	1	0.801	0.770	0.784
LIVER			IN 51-80	2	13	16	20	12			
Hepatocellular			IN 81-104	1	6	3	2	0			
			IN 81-104	2	33	29	26	19			
			IN 105-105	1	1	0	1	2			
			IN 105-105	2	22	28	11	8			
			FA 89	1	0	1	0	0			
			FA 89	2	51	44	35	22			
Spontaneous tumor pct: 10%	in ctrl.	-	Total	-	8	4	3	3			

Organ: Gland

Tumor: pheochromocytoma + malignant pheochromocytoma

		IN 51-80	1	3	0	0	0	0.989	0.986	0.987
ADRENAL	(1600	}	IN 51-80	2	11	16	20	13		
Pheochromocytoma	(C41		IN 81-104	1	13	8	8	3		
	IN 81-104		2	25	25	20	16			
	IN 105-105		1	10	8	4	3			
	IN 105-105		2	13	20	8	7			
	FA 104		1	1	9	0	0			
	FA 104		2	26	28	13	10			
	- Total		-	27	16	12	6			
Spontaneous tumor pct: 35%		in ctrl.	-							

Organ: Pituitary

Tumor: ParsDistalis: adenoma + carcinoma

PITUITARY	(1610	}	IN 0-50	1	1	0	1	0	0.767	0.751	0.757
Pars Distalis	(C33)		IN 0-50	2	0	0	0	0			
			IN 51-80	1	7	10	18	4			
			IN 51-80	2	3	5	3	6			
			IN 81-104	1	17	22	18	14			
			IN 81-104	2	7	7	8	4			
			IN 105-105	1	13	20	9	7			
			IN 105-105	2	10	8	3	3			
			FA 53	1	0	0	1	0			
			FA 53	2	75	77	58	42			
			FA 62	1	0	0	0	1			
			FA 62	2	73	74	53	39			
			FA 66	1	1	0	0	0			
			FA 66	2	72	73	50	38			
			FA 69	1	0	0	1	0			
			FA 69	2	72	72	47	35			
			FA 71	1	0	0	1	1			
			FA 71	2	71	68	41	32			
			FA 74	1	3	0	0	0			
			FA 74	2	68	67	43	31			
			FA 77	1	0	1	0	0			
			FA 77	2	66	65	42	31			
			FA 79	1	0	0	0	1			
			FA 79	2	64	65	41	30			
			FA 81	1	0	1	0	0			
			FA 81	2	62	60	40	29			
			FA 82	1	1	0	0	1			
			FA 82	2	61	58	40	27			
			FA 83	1	1	0	0	0			
			FA 83	2	60	58	39	27			
			FA 84	1	0	1	0	0			
			FA 84	2	59	56	39	27			
			FA 85	1	1	0	1	0			
			FA 85	2	58	52	37	25			
			FA 87	1	2	1	0	0			
			FA 87	2	53	47	36	24			
			FA 88	1	1	0	0	0			
			FA 88	2	51	46	35	22			

FA 97	1	2	0	0	0
FA 97	2	42	38	29	14
FA 98	1	1	0	0	0
FA 98	2	41	38	29	12
FA 99	1	1	0	1	0
FA 99	2	39	37	27	12
FA 100	1	3	1	0	0
FA 100	2	33	35	24	11
FA 103	1	1	0	0	0
FA 103	2	29	28	14	10
FA 104	1	1	0	0	0
FA 104	2	26	28	13	10
Spontaneous tumor pct: 74% in ctrl. - Total	-	57	57	47	31

Organ: Kidney

Tumor: tubular cell: adenoma + carcinoma

KIDNEY	(1620	)	IN 51-80	1	1	0	1	0	0.309	0.253	0.276
Tabular	(C31	)	IN 51-80	2	13	16	19	13			
			IN 81-104	1	0	1	1	1			
			IN 81-104	2	39	32	27	18			
			IN 105-105	1	0	2	1	0			
			IN 105-105	2	23	26	11	10			
Spontaneous tumor pct: 1% in ctrl. - Total	-			-	1	3	3	1			

Organ: Pancreas

Tumor: acinar cell: adenoma + carcinoma

PANCREAS	(1670	)	IN 51-80	1	0	0	0	1	0.310	0.267	0.285
Acinar Cell	(C38	)	IN 51-80	2	14	16	20	12			
			IN 81-104	1	2	1	3	1			
			IN 81-104	2	37	32	25	18			
			IN 105-105	1	2	2	0	1			
			IN 105-105	2	21	26	12	9			
Spontaneous tumor pct: 5% in ctrl. - Total	-			-	4	3	3	3			

Organ: Pancreas

Tumor: islet cell: adenoma + carcinoma

PANCREAS	(1670	)	IN 51-80	1	1	1	0	0	0.997	0.996	0.996
Islet Cell	(C39	)	IN 51-80	2	13	15	20	13			
			IN 81-104	1	11	3	6	0			
			IN 81-104	2	28	30	22	19			
			IN 105-105	1	6	9	2	1			
			IN 105-105	2	17	19	10	9			
Spontaneous tumor pct: 23% in ctrl. - Total	-			-	18	13	8	1			

Organ: Skin

Tumor: squamous cell: papilloma + carcinoma

SKIN	(1740	)	IN 81-104	1	2	0	0	0	1.000	0.975	0.980
Squamous Cell	(C2	)	IN 81-104	2	36	33	28	19			
			FA 102	1	1	0	0	0			
			FA 102	2	31	31	18	10			
Spontaneous tumor pct: 4% in ctrl. - Total	-			-	3	0	0	0			

Organ: Skin

Tumor: sebaceous cell: adenoma + carcinoma

SKIN	(1740	)	IN 81-104	1	1	2	1	0	0.857	0.806	0.829
Sebaceous Cell	(C3	)	IN 81-104	2	38	31	27	19			
			IN 105-105	1	1	0	0	0			
			IN 105-105	2	22	28	12	10			
Spontaneous tumor pct: 3% in ctrl. - Total	-			-	2	2	1	0			

Organ: Skin

Tumor: fibroma + fibrosarcoma

SKIN	(1740	)	IN 51-80	1	0	1	0	1	0.272	0.241	0.254
Fibroma + Fibrosarcoma	(C5	)	IN 51-80	2	13	12	19	12			
			IN 81-104	1	0	2	0	1			
			IN 81-104	2	39	30	25	18			
			IN 105-105	1	3	4	2	1			
			IN 105-105	2	20	24	10	9			
			FA 52	1	1	0	0	0			
			FA 52	2	75	77	60	42			
			FA 61	1	0	1	0	0			
			FA 61	2	73	74	53	41			
			FA 72	1	0	0	1	0			
			FA 72	2	71	67	44	32			
			FA 79	1	0	1	0	0			
			FA 79	2	64	64	41	31			
			FA 80	1	0	1	0	0			
			FA 80	2	63	62	41	30			
			FA 93	1	0	0	1	0			
			FA 93	2	47	42	32	17			
			FA 95	1	0	1	0	0			
			FA 95	2	44	38	32	16			

	FA 99	1	0	0	2	0
	FA 99	2	40	37	26	12
Spontaneous tumor pct: 5%	in ctrl. - Total	-	4	11	6	3

Organ: Mammary Gland

Tumor: Adenoma + Fibroma+Fibroadenoma

MAMMARY GLAND	(1750)	IN 51-80	1	0	1	0	0	0.790	0.737	0.761
Adenoma + Fibroadenoma	(C11)	IN 51-80	2	14	15	20	13			
		IN 81-104	1	1	2	0	1			
		IN 81-104	2	37	31	28	18			
		FA 89	1	1	0	0	0			
		FA 89	2	50	45	35	22			
Spontaneous tumor pct: 3%	in ctrl. - Total	-	2	3	0	1				

Organ: Thyroid

Tumor: "C"-cell: adenoma +carcinoma

THYROID	(1780)	IN 51-80	1	0	0	1	1	0.677	0.635	0.654
C-Cell	(C37)	IN 51-80	2	14	16	19	12			
		IN 81-104	1	4	2	1	1			
		IN 81-104	2	35	31	27	18			
		IN 105-105	1	0	4	0	0			
		IN 105-105	2	23	24	12	10			
Spontaneous tumor pct: 5%	in ctrl. - Total	-	4	6	2	2				

Organ: Prostate

Tumor: adenoma + carcinoma

PROSTATE	(1920)	IN 81-104	1	1	4	2	0	0.649	0.596	0.621
Adenoma + Carcinoma	(C46)	IN 81-104	2	38	29	25	19			
		IN 105-105	1	1	0	0	0			
		IN 105-105	2	22	28	12	10			
		FA 100	1	0	0	1	0			
		FA 100	2	36	36	23	11			
Spontaneous tumor pct: 3%	in ctrl. - Total	-	2	4	3	0				

Organ: All Organs

Tumor: hemangioma

All organs	(C14)	IN 51-80	1	0	1	0	0	0.754	0.682	0.716
Hemangioma	(C14)	IN 51-80	2	14	15	20	13			
		IN 81-104	1	1	0	0	0			
		IN 81-104	2	38	33	28	19			
		IN 105-105	1	0	1	1	0			
		IN 105-105	2	23	27	11	10			
Spontaneous tumor pct: 1%	in ctrl. - Total	-	1	2	1	0				

Organ: All Organs

Tumor: hemangiosarcoma

All Organs	(C15)	IN 81-104	1	0	1	0	0	0.689	0.621	0.655
Hemangiosarcoma	(C15)	IN 81-104	2	38	32	27	19			
		IN 105-105	1	0	2	0	0			
		IN 105-105	2	23	26	12	10			
		FA 99	1	1	0	0	0			
		FA 99	2	39	37	28	12			
		FA 101	1	0	0	1	0			
		FA 101	2	32	34	21	11			
Spontaneous tumor pct: 1%	in ctrl. - Total	-	1	3	1	0				

Organ: All Organs

Tumor: hemangioma + hemangiosarcoma

All Organs	(C16)	IN 51-80	1	0	1	0	0	0.797	0.752	0.773
Hema-gioma-ngiosarcoma	(C16)	IN 51-80	2	26	31	37	37			
		IN 81-104	1	1	1	0	0			
		IN 81-104	2	43	39	37	26			
		IN 105-105	1	0	3	1	0			
		IN 105-105	2	26	29	13	12			
		FA 99	1	1	0	0	0			
		FA 99	2	43	43	32	15			
		FA 101	1	0	0	1	0			
		FA 101	2	36	40	23	14			
Spontaneous tumor pct: 2%	in ctrl. - Total	-	2	5	2	0				

Table 18

Combined organ and tumor analyses
 Analysis of Carcinogenic Potential in Female Rat
 - Test of Dose-Response (Tumor) Positive Linear Trend
 Dose Levels Included: CTRL LOW MED HIGH (0, 0.5, 1.0, 1.5)

Study No. 97095
 Run Date & Time: July 3, 2001 (13:20)
 Source: C:\N21-341\RAT\FEMALE\XAnimalx.txt
 Note: Dose Levels Included: CTRL LOW MED HIGH (0 0.5 1 1.5)
 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 -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
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Organ: Adrenal

Tumor: cortical adenoma + carcinoma

ADRENAL	(1600	}	IN 51-80	1	1	1	0	1	0.620 0.578 0.671		
Cortex	(C40		IN 51-80	2	22	25	22	9			
			IN 81-104	1	2	1	2	1			
			IN 81-104	2	38	46	23	10			
			IN 105-105	1	1	3	1	0			
			IN 105-105	2	17	29	16	0			
			IN INTERIM	1	1	0	0	0			
			IN INTERIM	2	9	0	0	10			
			FA 95	1	1	0	0	0			
			FA 95	2	45	55	25	11			
			FA 96	1	1	0	0	0			
			FA 96	2	42	50	24	11			
			FA 103	1	0	0	1	0			
			FA 103	2	30	35	19	10			
			FA 104	1	0	1	0	0			
			FA 104	2	29	34	18	10			
Spontaneous tumor pct: 8%				in ctrl.	-	Total	-	7	6	4	2

Organ: Adrenal

Tumor: pheochromocytoma + malignant pheochromocytoma

ADRENAL	(1600	}	IN 51-80	1	0	1	1	1	0.155 0.131 0.181		
Pheochromocytoma	(C41		IN 51-80	2	20	25	21	9			
			IN 81-104	1	2	7	5	0			
			IN 81-104	2	40	41	23	10			
			IN 105-105	1	2	5	4	0			
			IN 105-105	2	16	27	13	0			
			FA 56	1	1	0	0	0			
			FA 56	2	91	106	66	31			
			FA 62	1	1	0	0	0			
			FA 62	2	86	101	63	29			
			FA 77	1	1	0	0	0			
			FA 77	2	72	85	48	24			
			FA 97	1	0	0	0	1			
			FA 97	2	41	49	24	10			
Spontaneous tumor pct: 8%				in ctrl.	-	Total	-	7	13	10	2

Organ: Pituitary

Tumor: ParsDistalis: adenoma + carcinoma

PITUITARY	(1610	}	IN 51-80	1	9	13	6	3	0.130 0.121 0.140
Pars Distalis	(C33		IN 51-80	2	3	1	1	0	
			IN 81-104	1	13	13	13	4	
			IN 81-104	2	2	3	0	1	
			IN 105-105	1	17	29	17	0	
			IN 105-105	2	1	1	0	0	
			IN INTERIM	1	9	0	0	9	
			IN INTERIM	2	1	0	0	1	
			FA 56	1	0	1	0	0	
			FA 56	2	92	105	66	31	
			FA 57	1	0	1	0	0	
			FA 57	2	91	104	66	31	
			FA 58	1	1	0	0	0	
			FA 58	2	90	104	66	31	
			FA 59	1	1	0	0	0	
			FA 59	2	89	104	66	31	
			FA 60	1	2	1	0	0	
			FA 60	2	87	103	65	30	
			FA 61	1	0	0	2	1	
			FA 61	2	87	102	63	29	
			FA 62	1	1	0	2	0	
			FA 62	2	86	101	61	29	
			FA 63	1	0	0	1	0	
			FA 63	2	85	100	60	29	

FA 64	1	0	1	0	0
FA 64	2	84	99	60	29
FA 65	1	0	0	1	1
FA 65	2	84	99	58	28
FA 67	1	0	0	1	0
FA 67	2	83	99	57	28
FA 68	1	1	0	0	0
FA 68	2	82	98	57	28
FA 69	1	1	0	1	0
FA 69	2	81	98	56	28
FA 70	1	1	0	0	2
FA 70	2	80	98	56	26
FA 71	1	1	0	0	1
FA 71	2	79	97	56	25
FA 72	1	1	1	1	0
FA 72	2	78	95	54	25
FA 73	1	0	1	0	1
FA 73	2	76	93	53	24
FA 74	1	1	1	1	0
FA 74	2	74	91	51	24
FA 75	1	0	1	0	0
FA 75	2	74	87	51	24
FA 76	1	0	1	2	0
FA 76	2	73	85	49	24
FA 77	1	0	1	1	0
FA 77	2	73	84	47	24
FA 78	1	0	1	1	0
FA 78	2	72	83	46	23
FA 79	1	0	1	0	0
FA 79	2	71	81	46	23
FA 80	1	0	0	1	1
FA 80	2	71	80	45	21
FA 81	1	0	1	1	0
FA 81	2	70	79	44	21
FA 82	1	1	1	1	0
FA 82	2	66	77	41	21
FA 83	1	0	3	0	2
FA 83	2	66	74	41	19
FA 84	1	0	1	1	0
FA 84	2	66	72	40	19
FA 85	1	3	1	1	0
FA 85	2	62	71	39	19
FA 86	1	0	2	0	1
FA 86	2	61	68	39	17
FA 87	1	1	2	1	1
FA 87	2	60	65	37	15
FA 88	1	1	2	1	0
FA 88	2	59	63	36	14
FA 89	1	1	0	2	0
FA 89	2	58	63	34	13
FA 90	1	0	1	0	0
FA 90	2	58	62	34	13
FA 91	1	3	1	1	0
FA 91	2	55	61	32	13
FA 92	1	2	0	2	1
FA 92	2	52	60	28	12
FA 93	1	1	1	0	1
FA 93	2	48	59	28	11
FA 94	1	1	3	1	0
FA 94	2	46	55	25	11
FA 95	1	1	4	1	0
FA 95	2	45	51	24	11
FA 96	1	2	0	0	0
FA 96	2	41	50	24	11
FA 97	1	1	0	0	0
FA 97	2	40	49	24	11
FA 98	1	1	2	0	0
FA 98	2	38	46	24	10
FA 99	1	2	2	1	0
FA 99	2	35	44	23	10
FA 100	1	2	2	1	0
FA 100	2	33	40	21	10
FA 101	1	2	1	0	0
FA 101	2	31	37	21	10
FA 102	1	1	0	0	0
FA 102	2	30	36	21	10
FA 104	1	1	2	0	0
FA 104	2	28	33	18	10
FA 105	1	0	2	0	0
FA 105	2	28	30	17	10
Spontaneous tumor pct: **% in ctrl. - Total	-	86101	66	29	

Organ: Kidney

Tumor: tubular cell: adenoma + carcinoma

KIDNEY	(1620	)	IN 81-104	1	1	2	0	0
Tabular	(C31	)	IN 81-104	2	41	46	28	11
			IN 105-105	1	1	0	0	0
			IN 105-105	2	17	32	17	0
Spontaneous tumor pct: 2% in ctrl. - Total	-			-	2	2	0	0

0.943 0.890 0.963

Organ: Skin

Tumor: fibroma + fibrosarcoma

SKIN	(1740	)	IN 51-80	1	0	1	0	0
Fibroma + Fibrosarcoma	(C5	)	IN 51-80	2	23	24	21	10
			IN 81-104	1	0	0	1	0
			IN 81-104	2	42	48	27	11
			IN 105-105	1	2	0	0	0
			IN 105-105	2	16	32	17	0
FA 61				1	0	1	0	0
FA 61				2	87101	65	30	

0.669 0.593 0.755

	FA 64	1	0	0	1	0
	FA 64	2	84	100	59	29
Spontaneous tumor pct: 2%	in ctrl.	-	2	2	2	0
	- Total	-				

Organ: Thyroid

Tumor: follicular cell: adenoma + carcinoma

THYROID	(1780	)	IN 51-80	1	1	0	0	0	0.839 0.769 0.897
Follicular cell	(C36	)	IN 51-80	2	22	26	22	10	
			IN 81-104	1	0	1	1	0	
			IN 81-104	2	41	47	27	11	
			FA 93	1	1	0	0	0	
			FA 93	2	48	60	28	12	
Spontaneous tumor pct: 2%	in ctrl.	-	- Total	-	2	1	1	0	

Organ: Thyroid

Tumor: "C"-cell: adenoma + carcinoma

THYROID	(1780	)	IN 51-80	1	1	1	1	0.301 0.260 0.346
C-Cell	(C37	)	IN 51-80	2	22	25	21	
			IN 81-104	1	2	3	1	
			IN 81-104	2	39	45	27	
			IN 105-105	1	0	1	2	
			IN 105-105	2	18	31	15	
			IN INTERIM	1	1	0	0	
			IN INTERIM	2	9	0	0	
			FA 93	1	1	0	0	
			FA 93	2	48	60	28	
Spontaneous tumor pct: 6%	in ctrl.	-	- Total	-	5	5	4	

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Table 19

Combined organ and tumor analyses Analysis of Carcinogenic Potential in Female Rat Test of Dose-Response (Tumor) Positive Linear Trend Dose Levels Included: CTRL LOW MED (0, 0.5, 1.0) Excluding HIGH dose group

Study No. 97095
Run Date & Time: July 5, 2001 (15:33)
Source: C:\N21-341\RAT\FEMALE\XAnimalX.txt
Note: Dose Levels Included: CTRL LOW MED (0 0.5 1)
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 -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
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Organ: Adrenal

Tumor: cortical adenoma + carcinoma

ADRENAL	(1600	)	IN 51-80	1	1 1 0	0.661 0.599 0.723
Cortex	(C40	)	IN 51-80	2	22 25 22	
			IN 81-104	1	2 1 2	
			IN 81-104	2	38 46 25	
			IN 105-105	1	1 3 1	
			IN 105-105	2	17 29 16	
			IN INTERIM	1	1 0 0	
			IN INTERIM	2	9 0 0	
			FA 95	1	1 0 0	
			FA 95	2	45 55 25	
			FA 96	1	1 0 0	
			FA 96	2	42 50 24	
			FA 103	1	0 0 1	
			FA 103	2	30 35 19	
			FA 104	1	0 1 0	
			FA 104	2	29 34 18	
Spontaneous tumor pct: 8% in ctrl. - Total					7 6 4	

Organ: Adrenal

Tumor: pheochromocytoma + malignant pheochromocytoma

ADRENAL	(1600	)	IN 51-80	1	0 1 1	0.119 0.095 0.146
Pheochromocytoma	(C41	)	IN 51-80	2	20 25 21	
			IN 81-104	1	2 7 5	
			IN 81-104	2	40 41 23	
			IN 105-105	1	2 5 4	
			IN 105-105	2	16 27 13	
			FA 56	1	1 0 0	
			FA 56	2	91106 66	
			FA 62	1	1 0 0	
			FA 62	2	86101 63	
			FA 77	1	1 0 0	
			FA 77	2	72 85 48	
Spontaneous tumor pct: 8% in ctrl. - Total					7 13 10	

Organ: Pituitary

Tumor: ParsDistalis: adenoma + carcinoma

PITUITARY	(1610	)	IN 51-80	1	9 13 6	0.107 0.096 0.118
Pars Distalis	(C33	)	IN 51-80	2	3 1 1	
			IN 81-104	1	13 13 13	
			IN 81-104	2	2 3 0	
			IN 105-105	1	17 29 17	
			IN 105-105	2	1 1 0	
			IN INTERIM	1	9 0 0	
			IN INTERIM	2	1 0 0	
			FA 56	1	0 1 0	
			FA 56	2	92105 66	
			FA 57	1	0 1 0	
			FA 57	2	91104 66	
			FA 58	1	1 0 0	
			FA 58	2	90104 66	
			FA 59	1	1 0 0	
			FA 59	2	89104 66	
			FA 60	1	2 1 0	
			FA 60	2	87103 65	
			FA 61	1	0 0 2	
			FA 61	2	87102 63	
			FA 62	1	1 0 2	
			FA 62	2	86101 61	
			FA 63	1	0 0 1	

FA 63	2	85100	60
FA 64	1	0	1
FA 64	2	84	99
FA 65	1	0	0
FA 65	2	84	99
FA 67	1	0	0
FA 67	2	83	99
FA 68	1	1	0
FA 68	2	82	98
FA 69	1	1	0
FA 69	2	81	98
FA 70	1	1	0
FA 70	2	80	98
FA 71	1	1	0
FA 71	2	79	97
FA 72	1	1	1
FA 72	2	78	95
FA 73	1	0	1
FA 73	2	76	93
FA 74	1	1	1
FA 74	2	74	91
FA 75	1	0	1
FA 75	2	74	87
FA 76	1	0	1
FA 76	2	73	85
FA 77	1	0	1
FA 77	2	73	84
FA 78	1	0	1
FA 78	2	72	83
FA 79	1	0	1
FA 79	2	71	81
FA 80	1	0	0
FA 80	2	71	80
FA 81	1	0	1
FA 81	2	70	79
FA 82	1	1	1
FA 82	2	66	77
FA 83	1	0	3
FA 83	2	66	74
FA 84	1	0	1
FA 84	2	66	72
FA 85	1	3	1
FA 85	2	62	71
FA 86	1	0	2
FA 86	2	61	68
FA 87	1	1	2
FA 87	2	60	65
FA 88	1	1	2
FA 88	2	59	63
FA 89	1	1	0
FA 89	2	58	63
FA 90	1	0	1
FA 90	2	58	62
FA 91	1	3	1
FA 91	2	55	61
FA 92	1	2	0
FA 92	2	52	60
FA 93	1	1	1
FA 93	2	48	59
FA 94	1	1	3
FA 94	2	46	55
FA 95	1	1	4
FA 95	2	45	51
FA 96	1	2	0
FA 96	2	41	50
FA 97	1	1	0
FA 97	2	40	49
FA 98	1	1	2
FA 98	2	38	46
FA 99	1	2	2
FA 99	2	35	44
FA 100	1	2	2
FA 100	2	33	40
FA 101	1	2	1
FA 101	2	31	37
FA 102	1	1	0
FA 102	2	30	36
FA 104	1	1	2
FA 104	2	28	33
FA 105	1	0	2
FA 105	2	28	30
Spontaneous tumor pct: **% in ctrl. - Total	-	86101	66

Organ: Kidney

Tumor: tubular cell: adenoma + carcinoma

KIDNEY	(1620	)	IN 81-104	1	1	2	0
Tabular	(C31	)	IN 81-104	2	41	46	28
			IN 105-105	1	1	0	0
			IN 105-105	2	17	32	17
Spontaneous tumor pct: 2% in ctrl. - Total	-			-	2	2	0

0.926 0.862 0.960

Organ: Skin

Tumor: fibroma + fibrosarcoma

SKIN	(1740	)	IN 51-80	1	0	1	0
Fibroma + Fibrosarcoma	(C5	)	IN 51-80	2	23	24	21
			IN 81-104	1	0	0	1
			IN 81-104	2	42	48	27
			IN 105-105	1	2	0	0
			IN 105-105	2	16	32	17
FA 61				1	0	1	0

0.526 0.422 0.634

	FA 61	2	87101	65
	FA 64	1	0	0
	FA 64	2	84100	59
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-
			2	2

Organ: Thyroid

Tumor: follicular cell: adenoma + carcinoma

THYROID	(1780	)	IN 51-80	1	1	0	0	
Follicular cell	(C36	)	IN 51-80	2	22	26	22	0.760 0.655 0.855
			IN 81-104	1	0	1	1	
			IN 81-104	2	41	47	27	
			FA 93	1	1	0	0	
			FA 93	2	48	60	28	
Spontaneous tumor pct: 2%	in ctrl.	-	Total	-	2	1	1	

Organ: Thyroid

Tumor: "C"-cell: adenoma + carcinoma

THYROID	(1780	)	IN 51-80	1	1	1	1	
C-cell	(C37	)	IN 51-80	2	22	25	21	0.438 0.367 0.513
			IN 81-104	1	2	3	1	
			IN 81-104	2	39	45	27	
			IN 105-105	1	0	1	2	
			IN 105-105	2	18	31	15	
			IN INTERIM	1	1	0	0	
			IN INTERIM	2	9	0	0	
			FA 93	1	1	0	0	
			FA 93	2	48	60	28	
Spontaneous tumor pct: 6%	in ctrl.	-	Total	-	5	5	4	

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APPEARS THIS WAY
ON ORIGINAL

Table 20

Combined organ and tumor analyses Analysis of Carcinogenic Potential in Male Mice Test of Dose-Response (Tumor) Positive Linear Trend Dose Levels Included: CTRL LOW MED HIGH (0, 6.25, 12.5, 25)

Study No. 97091
Run Date & Time: July 3, 2001 (15:19)
Source: C:\N21-341\MICE\MALE\XANIMA1X.TXT
Note: Dose Levels Included: CTRL LOW MED HIGH (0 6.25 12.5 25)
Missing value in Tumor-Caused Death is treated as tumor not causing death
Tumor Type: IN: Incidental (nonfatal) tumor, FA: Fatal tumor.

ORGAN/ISSUE 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)
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Organ: Adrenal

Tumor: cortical adenoma + carcinoma

ADRENAL(S)	(1	)	IN 81-104	1	1	0	0	0	0.601 0.538 0.551
Cortical	(C4	)	IN 81-104	2	4	6	5	7	
			IN 105-105	1	0	1	0	1	
			IN 105-105	2	9	12	8	8	
Spontaneous tumor pct: 6%			in ctrl. - Total		-	1	1	0	1

Organ: Subcutis

Tumor: fibroma + fibrosarcoma

SUBCUTIS	(202	)	IN 81-104	1	1	0	0	0	0.500 0.413 0.428
Fibroma + Fibrosarcoma	(C1	)	IN 81-104	2	4	6	5	6	
			FA 104	1	0	0	0	1	
			FA 104	2	9	13	8	9	
Spontaneous tumor pct: 6%			in ctrl. - Total		-	1	0	0	1

Organ: Liver

Tumor: hepatocellular adenoma + carcinoma

LIVER	(21	)	IN 0-50	1	0	0	1	0	0.722 0.698 0.702
Hepatocellular	(C3	)	IN 0-50	2	0	0	0	0	
			IN 51-80	1	0	1	2	2	
			IN 51-80	2	0	0	1	0	
			IN 81-104	1	2	2	2	4	
			IN 81-104	2	2	1	1	1	
			IN 105-105	1	9	12	8	8	
			IN 105-105	2	0	1	0	1	
			FA 68	1	1	0	0	0	
			FA 68	2	16	21	16	18	
			FA 69	1	1	0	0	0	
			FA 69	2	15	21	16	17	
			FA 74	1	1	0	0	0	
			FA 74	2	14	21	15	17	
			FA 78	1	0	1	0	0	
			FA 78	2	14	19	13	17	
			FA 84	1	0	1	0	0	
			FA 84	2	14	18	13	15	
			FA 87	1	0	0	1	0	
			FA 87	2	14	18	12	15	
			FA 90	1	0	0	0	1	
			FA 90	2	13	16	12	13	
			FA 91	1	0	1	0	0	
			FA 91	2	13	15	12	13	
			FA 92	1	0	0	1	0	
			FA 92	2	13	15	11	13	
			FA 93	1	1	0	0	0	
			FA 93	2	12	15	10	13	
			FA 101	1	0	0	0	1	
			FA 101	2	9	14	9	10	
			FA 102	1	0	1	0	0	
			FA 102	2	9	13	9	10	
Spontaneous tumor pct: 88%			in ctrl. - Total		-	15	19	15	16

Organ: Pituitary

Tumor: ParsDistalis: adenoma + carcinoma

PITUITARY	(35	)	IN 81-104	1	0	0	1	0	0.729 0.689 0.700
Hepatocellular	(C3	)	IN 81-104	2	5	6	4	7	
			IN 105-105	1	0	2	0	0	
			IN 105-105	2	9	11	8	9	
Spontaneous tumor pct: <= 1% in ctrl. - Total					-	0	2	1	0

Organ: All organs

Tumor: hemagioma

All organs	(C14	)	IN 51-80	1	0	0	1	0	0.630 0.596 0.611
Fibroma + Fibrosarcoma	(C1	)	IN 51-80	2	3	2	2	2	
			IN 81-104	1	0	1	0	0	
			IN 81-104	2	5	5	5	7	
Spontaneous tumor pct: <= 1% in ctrl.			- Total	-	0	1	1	0	

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APPEARS THIS WAY
ON ORIGINAL

Table 21

Combined organ and tumor analyses Analysis of Carcinogenic Potential in Female Mice Test of Dose-Response (Tumor) Positive Linear Trend Dose Levels Included: CTRL LOW MED HIGH (0, 12.5, 25, 50)

Study No. 97091
 Run Date & Time: July 3, 2001 (16:03)
 Source: C:\N21-341\MICE\FEMALE\XANIMA\X.txt
 Note: Dose Levels Included: CTRL LOW MED HIGH (0 12.5 25 50)
 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 -----TABLES-----	EXACT ASYMPT ASYMPT PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
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Organ: All organs

Tumor: hemangioma

All organs	(14)	IN 51-80	1	0 0 1 0	0.520 0.408 0.418
Hemangioma	(14)	IN 51-80	2	1 0 2 0	
		IN 102-103	1	0 1 0 0	
		IN 102-103	2	4 3 3 1	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 1 0	

Organ: Liver

Tumor: hepatocellular adenoma + carcinoma

LIVER	(21)	IN 51-80	1	1 0 1 0	0.569 0.500 0.505
Hepatocellular	(30)	IN 51-80	2	0 0 2 0	
		IN 81-101	1	0 0 1 1	
		IN 81-101	2	1 0 1 0	
		IN 102-103	1	2 2 2 0	
		IN 102-103	2	2 2 1 1	
Spontaneous tumor pct: 50% in ctrl. - Total			-	3 2 4 1	

Organ: Pituitary

Tumor: ParsDistalis: adenoma + carcinoma

PITUITARY	(35)	IN 51-80	1	0 0 1 0	0.504 0.443 0.448
Pars Distalis	(33)	IN 51-80	2	1 0 1 0	
		IN 81-101	1	1 0 1 0	
		IN 81-101	2	0 0 1 1	
		IN 102-103	1	2 1 1 1	
		IN 102-103	2	2 3 2 0	
		FA 59	1	0 0 1 0	
		FA 59	2	6 4 7 2	
Spontaneous tumor pct: 50% in ctrl. - Total			-	3 1 4 1	

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 ON ORIGINAL

References

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4. Lin, K.K. and M.W. Ali (1994): "Statistical Review and Evaluation of Animal Tumorigenicity Studies", Statistics in Pharmaceutical Industry, Marcel Decker, Inc., pp. 19-57.
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Statistical Review and Evaluation

NDA 21-314

Name of the Drug: Vadecoxib

Name of the Applicant: G.D. Searle and Co.

Indication: Acute pain in _____ Dosing Analgesia

Reviewer: Jyoti Zalkikar, Ph.D.

Summary of Statistical Findings

[The following text is heavily redacted with horizontal lines and is illegible.]

**53 page(s) have been
removed because it
contains trade secret
and/or confidential
information that is not
disclosable.**

2 - 54

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jyoti Zalkikar
10/26/01 05:08:46 PM
BIOMETRICS

Stan Lin
11/9/01 03:25:13 PM
UNKNOWN