NDA 20-895

Sildenafil

Appendix D-Female-Mice

Female Mice

NDA 20-895, Sildenafil
Appendix D-Female-Mice

Table I_D-Female-Mice

Case Where All Doses Are Included

Test for Positive Dose-Response (Tumor) Linear Trend
Species: Mouse
Sex: Female
Sorted by: Organ Name

15:05 Monday, February 2, 1998

Organ Code	Organ Name	Tumor Code	Tumor Name	Exact-P	Asymp-P	AsyCor-P
56	Abdomen	348	B-HAEMANGIOMA	0.1458	0.0118	0.0170
7	Adrenal	285	B-SUBCAPSULAR CELL ADENOM	1.0000	0.7319	0.7771
37	Harderian gland	258	B-ADENOMA	0.9535	0.9104	0.9156
1	Kidney	266	B-RENAL TUBULE ADENOMA	1.0000	0.7319	0.7771
3	Liver	332	B-HAEMANGIOMA	0.4710	0.4597	0.5145
33	Lungs	154	B-BRONCHIOLAR-ALVEOLAR AD	0.3570	0.3467	0.3542
33	Lungs	149	M-BRONCHIOLAR-ALVEOLAR CA	0.3670	0.3767	0.3872
58	Lymphoreticular	244	M-HISTIOCYTIC SARCOMA	0.3001	0.3299	0.3445
58	Lymphoreticular	234	M-IMMUNOBLASTIC LYMPHOMA	0.5625	0.2620	0.2759
58	Lymphoreticular	183	M-LYMPHOBLASTIC LYMPHOMA	0.2908	0.2812	0.2875
16	Ovaries	209	B-CYSTADENOMA	0.4794	0.4707	0.4818
16	Ovaries	246	B-SEX CORD/STROMAL TUMOUR	0.7605	0.7184	0.7461
16	Ovaries	407	B-TERATOMA	1.0000	0.8073	0.8438
31	Skin and adnexa	259	M-ADENOCARCINOMA, MAMMARY	1.0000	0.7310	0.7783
31	Skin and adnexa	204	M-FIBROUS HISTIOCYTOMA, M	1.0000	0.8073	0.8438
19	Spleen	330	B-HAEMANGIOMA	0.3750	0.4028	0.4594
22	Stomach	272	B-SQUAMOUS CELL PAPILLOMA	1.0000	0.7319	0.7771
22	Stomach	270	M-SQUAMOUS CELL CARCINOMA	1.0000	0.8114	0.8381
32	Thymus	359	M-THYMOMA, EPITHELIAL PRE	1.0000	0.8517	0.8710
9	Thyroid	331	M-FOLLICULAR CELL CARCINO	0.6047	0.7032	0.7181
17	Uterus	264	B-HAEMANGIOMA	1.0000	0.7310	0.7783
17	Uterus	287	B-LEIOMYOMA	0.2585	0.1731	0.1951
17	Uterus	284	M-STROMAL CELL SARCOMA	0.8448	0.7974	0.8086
18	Vagina	282	B-LEIOMYOMA	0.8400	0.7765	0.7890

Appendix D-Female Mice

Table II_D_Female_Mice
Case Where All Doses Are Included

Analysis of Carcinogenic Potential in Female Mouse
Test of Dose-Response (Tumor) Positive Linear Trend
Ted Guo, PH.D, CDER/FDA
Run Date & Time: January 29, 1998 (16:50)
Source: E:\MOUSE\f_mouse3.fil

Note: Dose Levels Included: CTRL1 CTRL2 LOW MED HIGH (0 0 3 10 30)
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 TYPES	TIME STRATA	ROW NO.	2xC_CONTINGENCY -----TABLE-----	EXACT PROB =PR(STATISTIC.GE.OBSERVED)	ASYMP TOTIC	ASYMP(CONTI NUITY CORR)
Kidney	(1)	IN	93-93	1	1 0 0 0 0	1.0000	0.7319	0.7771
B-RENAL TUBULE ADENOMA	(266)	IN	93-93	2	29 30 22 14 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	1 0 0 0 0			
Ovaries	(16)	IN	0-40	1	0 0 0 1 0	0.4794	0.4707	0.4818
B-CYSTADENOMA	(209)	IN	0-40	2	1 1 1 10 18			
		IN	41-64	1	0 0 0 0 1			
		IN	41-64	2	8 4 6 11 27			
		IN	93-93	1	1 0 1 0 0			
		IN	93-93	2	29 30 21 14 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	1 0 1 1 1			
Ovaries	(16)	IN	93-93	1	2 0 1 0 0	0.7605	0.7184	0.7461
B-SEX CORD/STROMAL TUMOUR	(246)	IN	93-93	2	28 30 21 14 0			
Spontaneous tumor rate 2% in ctrl.		-	Total	-	2 0 1 0 0			
Ovaries	(16)	IN	81-92	1	1 0 0 0 0	1.0000	0.8073	0.8438
B-TERATOMA	(407)	IN	81-92	2	9 8 19 8 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	1 0 0 0 0			
Uterus	(17)	FA	77	1	1 0 0 0 0	1.0000	0.7310	0.7783
B-HAEMANGIOMA	(264)	FA	77	2	36 35 29 15 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	1 0 0 0 0			
Uterus	(17)	IN	65-80	1	1 0 0 0 0	0.8448	0.7974	0.8086
M-STROMAL CELL SARCOMA	(284)	IN	65-80	2	5 12 7 11 9			
		IN	93-93	1	1 0 1 0 0			
		IN	93-93	2	29 30 21 14 0			
Spontaneous tumor rate 2% in ctrl.		-	Total	-	2 0 1 0 0			
Uterus	(17)	IN	81-92	1	0 0 1 0 0	0.2585	0.1731	0.1951
B-LEIOMYOMA	(287)	IN	81-92	2	10 8 18 8 0			
		IN	93-93	1	1 0 0 1 0			
		IN	93-93	2	29 30 22 13 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	1 0 1 1 0			
Vagina	(18)	IN	65-80	1	0 1 0 0 0	0.8400	0.7765	0.7890
B-LEIOMYOMA	(282)	IN	65-80	2	6 11 7 11 9			
		IN	81-92	1	0 0 1 0 0			
		IN	81-92	2	10 8 18 8 0			
Spontaneous tumor rate LE 1% in ctrl.		-	Total	-	0 1 1 0 0			

Appendix D-Female Mice: Table II_Female Mice (Continued)

Spleen	(19)	IN 93-93	1	0	0	1	0	0	0.3750	0.4028	0.4594
B-HAEMANGIOMA	(330)	IN 93-93	2	30	30	21	14	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	0	0	1	0	0			
Stomach	(22)	IN 93-93	1	1	0	0	0	0	1.0000	0.8114	0.8381
M-SQUAMOUS CELL CARCINOMA	(270)	IN 93-93	2	29	30	22	14	0			
		FA 75	1	1	0	0	0	0			
		FA 75	2	37	36	32	16	0			
Spontaneous tumor rate 2% in ctrl. - Total			-	2	0	0	0	0			
Stomach	(22)	IN 93-93	1	1	0	0	0	0	1.0000	0.7319	0.7771
B-SQUAMOUS CELL PAPILLOMA	(272)	IN 93-93	2	29	30	22	14	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	1	0	0	0	0			
Liver	(3)	FA 65	1	0	0	1	0	0	0.4710	0.4597	0.5145
B-HAEMANGIOMA	(332)	FA 65	2	43	39	45	27	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	0	0	1	0	0			
Skin and adnexa	(31)	IN 81-92	1	0	1	0	0	0	1.0000	0.8073	0.8438
M-FIBROUS HISTIOCYTOMA, M	(204)	IN 81-92	2	10	7	19	8	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	0	1	0	0	0			
Skin and adnexa	(31)	FA 77	1	1	0	0	0	0	1.0000	0.7310	0.7783
M-ADENOCARCINOMA, MAMMARY	(259)	FA 77	2	36	35	29	15	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	1	0	0	0	0			
Thymus	(32)	IN 93-93	1	0	3	0	0	0	1.0000	0.8517	0.8710
M-THYMOMA, EPITHELIAL PRE	(359)	IN 93-93	2	29	27	21	12	0			
Spontaneous tumor rate 3% in ctrl. - Total			-	0	3	0	0	0			
Lungs	(33)	IN 65-80	1	0	0	1	0	0	0.3670	0.3767	0.3872
M-BRONCHIOLAR-ALVEOLAR CA	(149)	IN 65-80	2	6	12	6	11	9			
		IN 93-93	1	1	4	1	3	0			
		IN 93-93	2	29	26	21	11	0			
		FA 48	1	0	0	1	0	0			
		FA 48	2	51	53	52	37	27			
		FA 78	1	0	0	1	0	0			
		FA 78	2	35	33	25	14	0			
Spontaneous tumor rate 5% in ctrl. - Total			-	1	4	4	3	0			
Lungs	(33)	IN 41-64	1	0	0	1	1	0	0.3570	0.3467	0.3542
B-BRONCHIOLAR-ALVEOLAR AD	(154)	IN 41-64	2	8	4	5	10	28			
		IN 65-80	1	0	0	0	0	1			
		IN 65-80	2	6	12	7	11	8			
		IN 81-92	1	0	0	2	1	0			
		IN 81-92	2	10	8	17	7	0			
		IN 93-93	1	2	2	4	1	0			
		IN 93-93	2	28	28	18	13	0			
Spontaneous tumor rate 4% in ctrl. - Total			-	2	2	7	3	1			
Harderian gland	(37)	IN 65-80	1	0	0	1	0	0	0.9535	0.9104	0.9156
B-ADENOMA	(258)	IN 65-80	2	6	11	6	11	9			
		IN 81-92	1	0	0	1	0	0			
		IN 81-92	2	10	8	18	8	0			
		IN 93-93	1	3	4	1	0	0			
		IN 93-93	2	27	26	21	14	0			
Spontaneous tumor rate 6% in ctrl. - Total			-	3	4	3	0	0			
Abdomen	(56)	IN 93-93	1	0	0	0	1	0	0.1458	0.0118	0.0170
B-HAEMANGIOMA	(348)	IN 93-93	2	30	30	22	13	0			
Spontaneous tumor rate LE 1% in ctrl. - Total			-	0	0	0	1	0			
Lymphoreticular	(58)	IN 41-64	1	0	0	0	0	1	0.2908	0.2812	0.2875
M-LYMPHOBLASTIC LYMPHOMA	(183)	IN 41-64	2	8	4	6	10	27			
		IN 65-80	1	0	0	1	0	0			
		IN 65-80	2	6	12	6	11	9			
		IN 93-93	1	1	3	1	0	0			

Appendix D-Female Mice: Table II_Female Mice (Continued)

		IN 93-93	2	29	27	21	14	0			
		FA 24	1	0	0	0	0	1			
		FA 24	2	54	55	54	53	49			
		FA 29	1	0	1	0	0	0			
		FA 29	2	54	54	54	53	49			
		FA 43	1	0	0	0	1	0			
		FA 43	2	53	53	54	40	29			
		FA 79	1	1	0	1	0	0			
		FA 79	2	33	33	22	14	0			
Spontaneous tumor rate 5%	in ctrl.	- Total	-	2	4	3	1	2			
Lymphoreticular	(58)	IN 0-40	1	0	0	0	0	1	0.5625	0.2620	0.2759
M-IMMUNOBLASTIC LYMPHOMA	(234)	IN 0-40	2	1	1	1	11	17			
		IN 93-93	1	1	0	0	0	0			
		IN 93-93	2	29	30	22	14	0			
Spontaneous tumor rate LE 1%	in ctrl.	- Total	-	1	0	0	0	1			
Lymphoreticular	(58)	IN 93-93	1	1	0	0	1	0	0.3001	0.3299	0.3445
M-HISTIOCYTIC SARCOMA	(244)	IN 93-93	2	29	30	22	13	0			
		FA 40	1	0	1	0	0	0			
		FA 40	2	54	53	54	41	30			
		FA 64	1	0	0	0	1	0			
		FA 64	2	43	39	47	29	0			
		FA 76	1	0	0	1	0	0			
		FA 76	2	37	36	30	16	0			
		FA 78	1	1	0	0	0	0			
		FA 78	2	34	33	26	14	0			
Spontaneous tumor rate 3%	in ctrl.	- Total	-	2	1	1	2	0			
Adrenal	(7)	IN 93-93	1	1	0	0	0	0	1.0000	0.7319	0.7771
B-SUBCAPSULAR CELL ADENOM	(285)	IN 93-93	2	29	30	22	14	0			
Spontaneous tumor rate LE 1%	in ctrl.	- Total	-	1	0	0	0	0			
Thyroid	(9)	IN 65-80	1	0	0	1	0	0	0.6047	0.7032	0.7181
M-FOLLICULAR CELL CARCINO	(331)	IN 65-80	2	6	11	6	10	9			
Spontaneous tumor rate LE 1%	in ctrl.	- Total	-	0	0	1	0	0			

Appendix D-Female Mice: Table II_Female Mice (Continued)

NDA 20-895, Sildenafil
Appendix D-Female-Mice

Table III_D-Female-Mice
Case Where High Dose Is Excluded

Test for Positive Dose-Response (Tumor) Linear Trend
Species: Mouse
Sex: Female
Sorted by: Organ Name

15:05 Monday, February 2, 1998

Organ Code	Organ Name	Tumor Code	Tumor Name	Exact-P	Asymp-P	AsyCor-P
56	Abdomen	348	B-HAEMANGIOMA	0.1458	0.0118	0.0170
7	Adrenal	285	B-SUBCAPSULAR CELL ADENOM	1.0000	0.7319	0.7771
37	Harderian gland	258	B-ADENOMA	0.9415	0.9132	0.9201
1	Kidney	266	B-RENAL TUBULE ADENOMA	1.0000	0.7319	0.7771
3	Liver	332	B-HAEMANGIOMA	0.4710	0.4597	0.5145
33	Lungs	154	B-BRONCHIOLAR-ALVEOLAR AD	0.1611	0.1488	0.1577
33	Lungs	149	M-BRONCHIOLAR-ALVEOLAR CA	0.1414	0.1162	0.1247
58	Lymphoreticular	244	M-HISTIOCYTIC SARCOMA	0.1967	0.1490	0.1628
58	Lymphoreticular	234	M-IMMUNOBLASTIC LYMPHOMA	1.0000	0.7319	0.7771
58	Lymphoreticular	183	M-LYMPHOBLASTIC LYMPHOMA	0.7008	0.6829	0.6984
16	Ovaries	209	B-CYSTADENOMA	0.5126	0.4588	0.4909
16	Ovaries	246	B-SEX CORD/STROMAL TUMOUR	0.7605	0.7184	0.7461
16	Ovaries	407	B-TERATOMA	1.0000	0.8073	0.8438
31	Skin and adnexa	259	M-ADENOCARCINOMA, MAMMARY	1.0000	0.7310	0.7783
31	Skin and adnexa	204	M-FIBROUS HISTIOCYTOMA, M	1.0000	0.8073	0.8438
19	Spleen	330	B-HAEMANGIOMA	0.3750	0.4028	0.4594
22	Stomach	272	B-SQUAMOUS CELL PAPILLOMA	1.0000	0.7319	0.7771
22	Stomach	270	M-SQUAMOUS CELL CARCINOMA	1.0000	0.8114	0.8381
32	Thymus	359	M-THYMOMA, EPITHELIAL PRE	1.0000	0.8517	0.8710
9	Thyroid	331	M-FOLLICULAR CELL CARCINO	0.5000	0.5516	0.5970
17	Uterus	264	B-HAEMANGIOMA	1.0000	0.7310	0.7783
17	Uterus	287	B-LEIOMYOMA	0.2585	0.1731	0.1951
17	Uterus	284	M-STROMAL CELL SARCOMA	0.8059	0.7743	0.7965
18	Vagina	282	B-LEIOMYOMA	0.8000	0.7446	0.7724

Appendix D-Female Mice

Table IV_D_Female_Mice
Case Where the High Dose is Excluded

Analysis of Carcinogenic Potential in Female Mouse
Test of Dose-Response (Tumor) Positive Linear Trend
Ted Guo, PH.D, CDER/FDA
Run Date & Time: January 29, 1998 (17:14)
Source: E:\MOUSE\f_mouse3.fil

Note: Dose Levels Included: CTRL1 CTRL2 LOW MED (0 0 3 10)
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 TYPES	TIME STRATA	ROW NO.	2xC_CONTINGENCY -----TABLE-----	EXACT PROB =PR(STATISTIC.GE.OBSERVED)	ASYMP TOTIC	ASYMP(CONTI NUITY CORR)
Kidney	(1)	IN	93-93	1	1 0 0 0	1.0000	0.7319	0.7771
B-RENAL TUBULE ADENOMA	(266)	IN	93-93	2	29 30 22 14			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	1 0 0 0			
Ovaries	(16)	IN	0-40	1	0 0 0 1	0.5126	0.4588	0.4909
B-CYSTADENOMA	(209)	IN	0-40	2	1 1 1 10			
		IN	93-93	1	1 0 1 0			
		IN	93-93	2	29 30 21 14			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	1 0 1 1			
Ovaries	(16)	IN	93-93	1	2 0 1 0	0.7605	0.7184	0.7461
B-SEX CORD/STROMAL TUMOUR	(246)	IN	93-93	2	28 30 21 14			
Spontaneous tumor rate 2% in ctrl. -			Total	-	2 0 1 0			
Ovaries	(16)	IN	81-92	1	1 0 0 0	1.0000	0.8073	0.8438
B-TERATOMA	(407)	IN	81-92	2	9 8 19 8			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	1 0 0 0			
Uterus	(17)	FA	77	1	1 0 0 0	1.0000	0.7310	0.7783
B-HAEMANGIOMA	(264)	FA	77	2	36 35 29 15			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	1 0 0 0			
Uterus	(17)	IN	65-80	1	1 0 0 0	0.8059	0.7743	0.7965
M-STROMAL CELL SARCOMA	(284)	IN	65-80	2	5 12 7 11			
		IN	93-93	1	1 0 1 0			
		IN	93-93	2	29 30 21 14			
Spontaneous tumor rate 2% in ctrl. -			Total	-	2 0 1 0			
Uterus	(17)	IN	81-92	1	0 0 1 0	0.2585	0.1731	0.1951
B-LEIOMYOMA	(287)	IN	81-92	2	10 8 18 8			
		IN	93-93	1	1 0 0 1			
		IN	93-93	2	29 30 22 13			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	1 0 1 1			
Vagina	(18)	IN	65-80	1	0 1 0 0	0.8000	0.7446	0.7724
B-LEIOMYOMA	(282)	IN	65-80	2	6 11 7 11			
		IN	81-92	1	0 0 1 0			
		IN	81-92	2	10 8 18 8			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	0 1 1 0			
Spleen	(19)	IN	93-93	1	0 0 1 0	0.3750	0.4028	0.4594
B-HAEMANGIOMA	(330)	IN	93-93	2	30 30 21 14			
Spontaneous tumor rate LE 1% in ctrl. -			Total	-	0 0 1 0			

Stomach	(22	)	IN 93-93	1	1	0	0	0	1.0000	0.8114	0.8381
M-SQUAMOUS CELL CARCINOMA	(270	)	IN 93-93	2	29	30	22	14			
			FA 75	1	1	0	0	0			
			FA 75	2	37	36	32	16			
Spontaneous tumor rate 2%	in ctrl. - Total			-	2	0	0	0			
Stomach	(22	)	IN 93-93	1	1	0	0	0	1.0000	0.7319	0.7771
B-SQUAMOUS CELL PAPILLOMA	(272	)	IN 93-93	2	29	30	22	14			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	1	0	0	0			
Liver	(3	)	FA 65	1	0	0	1	0	0.4710	0.4597	0.5145
B-HAEMANGIOMA	(332	)	FA 65	2	43	39	45	27			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	0	0	1	0			
Skin and adnexa	(31	)	IN 81-92	1	0	1	0	0	1.0000	0.8073	0.8438
M-FIBROUS HISTIOCYTOMA, M	(204	)	IN 81-92	2	10	7	19	8			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	0	1	0	0			
Skin and adnexa	(31	)	FA 77	1	1	0	0	0	1.0000	0.7310	0.7783
M-ADENOCARCINOMA, MAMMARY	(259	)	FA 77	2	36	35	29	15			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	1	0	0	0			
Thymus	(32	)	IN 93-93	1	0	3	0	0	1.0000	0.8517	0.8710
M-THYMOMA, EPITHELIAL PRE	(359	)	IN 93-93	2	29	27	21	12			
Spontaneous tumor rate 3%	in ctrl. - Total			-	0	3	0	0			
Lungs	(33	)	IN 65-80	1	0	0	1	0	0.1414	0.1162	0.1247
M-BRONCHIOLAR-ALVEOLAR CA	(149	)	IN 65-80	2	6	12	6	11			
			IN 93-93	1	1	4	1	3			
			IN 93-93	2	29	26	21	11			
			FA 48	1	0	0	1	0			
			FA 48	2	51	53	52	37			
			FA 78	1	0	0	1	0			
			FA 78	2	35	33	25	14			
Spontaneous tumor rate 5%	in ctrl. - Total			-	1	4	4	3			
Lungs	(33	)	IN 41-64	1	0	0	1	1	0.1611	0.1488	0.1577
B-BRONCHIOLAR-ALVEOLAR AD	(154	)	IN 41-64	2	8	4	5	10			
			IN 81-92	1	0	0	2	1			
			IN 81-92	2	10	8	17	7			
			IN 93-93	1	2	2	4	1			
			IN 93-93	2	28	28	18	13			
Spontaneous tumor rate 4%	in ctrl. - Total			-	2	2	7	3			
Harderian gland	(37	)	IN 65-80	1	0	0	1	0	0.9415	0.9132	0.9201
B-ADENOMA	(258	)	IN 65-80	2	6	11	6	11			
			IN 81-92	1	0	0	1	0			
			IN 81-92	2	10	8	18	8			
			IN 93-93	1	3	4	1	0			
			IN 93-93	2	27	26	21	14			
Spontaneous tumor rate 6%	in ctrl. - Total			-	3	4	3	0			
Abdomen	(56	)	IN 93-93	1	0	0	0	1	0.1458	0.0118	0.0170
B-HAEMANGIOMA	(348	)	IN 93-93	2	30	30	22	13			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	0	0	0	1			
Lymphoreticular	(58	)	IN 65-80	1	0	0	1	0	0.7008	0.6829	0.6984
M-LYMPHOBLASTIC LYMPHOMA	(183	)	IN 65-80	2	6	12	6	11			
			IN 93-93	1	1	3	1	0			
			IN 93-93	2	29	27	21	14			
			FA 29	1	0	1	0	0			
			FA 29	2	54	54	54	53			
			FA 43	1	0	0	0	1			
			FA 43	2	53	53	54	40			
			FA 79	1	1	0	1	0			
			FA 79	2	33	33	22	14			
Spontaneous tumor rate 5%	in ctrl. - Total			-	2	4	3	1			
Lymphoreticular	(58	)	IN 93-93	1	1	0	0	0	1.0000	0.7319	0.7771
M-IMMUNOBLASTIC LYMPHOMA	(234	)	IN 93-93	2	29	30	22	14			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	1	0	0	0			

Appendix D-Female Mice: Table IV_Female Mice (Continued)

Lymphoreticular	(58	)	IN 93-93	1	1	0	0	1	0.1967	0.1490	0.1628
M-HISTIOCYTIC SARCOMA	(244	)	IN 93-93	2	29	30	22	13			
			FA 40	1	0	1	0	0			
			FA 40	2	54	53	54	41			
			FA 64	1	0	0	0	1			
			FA 64	2	43	39	47	29			
			FA 76	1	0	0	1	0			
			FA 76	2	37	36	30	16			
			FA 78	1	1	0	0	0			
			FA 78	2	34	33	26	14			
Spontaneous tumor rate 3%	in ctrl. - Total			-	2	1	1	2			
Adrenal	(7	)	IN 93-93	1	1	0	0	0	1.0000	0.7319	0.7771
B-SUBCAPSULAR CELL ADENOM	(285	)	IN 93-93	2	29	30	22	14			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	1	0	0	0			
Thyroid	(9	)	IN 65-80	1	0	0	1	0	0.5000	0.5516	0.5970
M-FOLLICULAR CELL CARCINO	(331	)	IN 65-80	2	6	11	6	10			
Spontaneous tumor rate LE 1% in ctrl. - Total				-	0	0	1	0			

Appendix D-Female Mice: Table IV_Female Mice (Continued)