

		IN 79-91	1	0	0	0	1	
		IN 79-91	2	15	5	12	12	
		IN 92-106	1	0	0	1	1	
		IN 92-106	2	48	30	25	15	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	1	2
DUODENUM	(DU	) FA 69	1	0	0	0	1	0.175 0.019 1.000
ADENOCARCINOMA	(386	) FA 69	2	96	47	50	40	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	0	1
EYES (L&R)	(EE	) IN 0-52	1	0	1	0	0	0.490 0.509 1.000
	(000	) IN 0-52	2	4	3	0	6	
		IN 53-78	1	0	1	0	0	
		IN 53-78	2	21	5	11	17	
		IN 79-91	1	0	0	0	1	
		IN 79-91	2	15	5	12	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	2	0	1
FEMUR AND MARROW	(FM	) IN 79-91	1	0	0	1	0	0.459 0.517 1.000
OSTEOMA	(459	) IN 79-91	2	15	5	11	14	
		IN 92-106	1	0	0	1	0	
		IN 92-106	2	48	30	26	17	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	2	0
GALL BLADDER	(GB	) IN 0-52	1	0	1	0	0	0.209 0.202 0.998
	(000	) IN 0-52	2	4	3	0	6	
		IN 53-78	1	1	1	0	1	
		IN 53-78	2	19	5	11	15	
		IN 79-91	1	1	0	1	2	
		IN 79-91	2	13	5	10	10	
		IN 92-106	1	1	0	2	1	
		IN 92-106	2	46	30	23	15	
Spontaneous tumor pct: 3% in ctrl. - Total				-	3	2	3	4
HARDERIAN GLANDS	(HG	) IN 53-78	1	0	0	1	0	0.102 0.108 1.000
CARCINOMA	(127	) IN 53-78	2	21	7	10	17	
		IN 92-106	1	0	0	0	1	
		IN 92-106	2	48	30	27	16	
		IN 107-107	1	0	1	0	0	
		IN 107-107	2	22	7	5	1	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	1	1
HARDERIAN GLANDS	(HG	) IN 53-78	1	1	0	0	1	0.798 0.794 1.000
ADENOMA	(203	) IN 53-78	2	20	7	11	16	
		IN 79-91	1	1	2	1	0	
		IN 79-91	2	14	3	11	14	
		IN 92-106	1	3	2	2	1	
		IN 92-106	2	45	28	25	16	
		IN 107-107	1	3	0	0	0	
		IN 107-107	2	19	8	5	1	
Spontaneous tumor pct: 7% in ctrl. - Total				-	8	4	3	2
H'POIETIC TUMOUR	(HP	) IN 53-78	1	1	0	0	0	0.886 0.879 0.999
MALIGNANT LYMPHOMA	(052	) IN 53-78	2	13	4	7	17	
		IN 79-91	1	0	0	1	1	
		IN 79-91	2	12	5	9	13	
		IN 92-106	1	4	2	2	1	
		IN 92-106	2	42	26	25	15	

IN 107-107	1	7	3	1	0	
IN 107-107	2	15	5	4	1	
FA 15	1	0	1	0	0	
FA 15	2	109	54	55	55	
FA 31	1	0	1	0	0	
FA 31	2	108	52	55	55	
FA 38	1	0	0	0	1	
FA 38	2	108	52	55	52	
FA 53	1	0	1	0	0	
FA 53	2	106	49	55	49	
FA 56	1	0	0	1	0	
FA 56	2	106	49	54	49	
FA 59	1	1	0	0	0	
FA 59	2	104	49	54	48	
FA 61	1	1	0	0	0	
FA 61	2	101	49	54	45	
FA 67	1	0	0	1	0	
FA 67	2	96	48	52	43	
FA 70	1	1	0	0	0	
FA 70	2	95	47	51	42	
FA 73	1	1	0	0	0	
FA 73	2	93	46	50	39	
FA 74	1	2	1	1	0	
FA 74	2	89	45	49	37	
FA 76	1	1	0	0	0	
FA 76	2	86	45	48	34	
FA 77	1	0	1	1	0	
FA 77	2	86	43	46	33	
FA 85	1	1	0	0	0	
FA 85	2	82	40	40	26	
FA 87	1	1	0	0	0	
FA 87	2	79	39	38	23	
FA 88	1	0	0	1	0	
FA 88	2	78	39	37	22	
FA 89	1	0	0	1	0	
FA 89	2	76	39	34	20	
FA 91	1	1	0	0	0	
FA 91	2	71	38	33	20	
FA 92	1	1	0	0	0	
FA 92	2	69	38	32	18	
FA 94	1	0	0	0	1	
FA 94	2	68	35	31	15	
FA 101	1	1	1	0	0	
FA 101	2	57	29	24	10	
FA 103	1	0	1	0	0	
FA 103	2	57	28	22	9	
Spontaneous tumor pct: 22%	in ctrl. - Total	-	24	12	10	4

H'POIETIC TUMOUR	(HP	) IN 92-106	1	1	0	0	0
HISTIOCYTIC SARCOMA	(299	) IN 92-106	2	46	30	27	17
		IN 107-107	1	1	0	0	0
		IN 107-107	2	21	8	5	1
		FA 60	1	1	0	0	0
		FA 60	2	103	49	54	47
		FA 61	1	0	1	0	0
		FA 61	2	102	48	54	45
		FA 79	1	1	0	0	0
		FA 79	2	84	43	44	32

0.992 0.952 1.000

	FA 80	1	0	1	0	0	
	FA 80	2	83	42	44	32	
	FA 89	1	1	0	0	0	
	FA 89	2	75	39	35	20	
	FA 100	1	1	0	0	0	
	FA 100	2	59	32	25	11	
Spontaneous tumor pct: 5%	in ctrl. - Total	-	6	2	0	0	
H'POIETIC TUMOUR	(HP) FA 37	1	0	0	0	1	0.200 0.028 1.000
PLASMA CELL LYMPHOMA	(347) FA 37	2	108	52	55	53	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	0	1	
ILEUM	(IL) IN 0-52	1	0	1	0	0	0.234 0.210 1.000
	(000) IN 0-52	2	4	3	0	6	
	IN 53-78	1	0	1	1	0	
	IN 53-78	2	21	5	9	17	
	IN 79-91	1	0	0	0	1	
	IN 79-91	2	15	5	12	12	
	IN 92-106	1	0	0	2	1	
	IN 92-106	2	48	30	23	15	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	2	3	2	
JEJUNUM	(JE) IN 53-78	1	1	0	0	0	0.112 0.072 1.000
	(000) IN 53-78	2	19	7	11	17	
	IN 79-91	1	0	0	0	1	
	IN 79-91	2	15	5	12	12	
	IN 92-106	1	0	0	1	1	
	IN 92-106	2	48	30	25	15	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	0	1	2	
L N	(LA) IN 92-106	1	0	0	1	0	0.355 0.416 1.000
	(000) IN 92-106	2	48	30	25	17	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	1	0	
L N	(LC) IN 0-52	1	0	1	0	0	0.774 0.824 1.000
	(000) IN 0-52	2	4	3	0	6	
	IN 53-78	1	1	0	0	0	
	IN 53-78	2	19	7	11	17	
	IN 92-106	1	0	0	1	0	
	IN 92-106	2	48	30	25	17	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	1	1	0	
LACHRYMAL GLANDS	(LG) IN 0-52	1	0	0	0	1	0.639 0.582 1.000
	(000) IN 0-52	2	4	5	0	4	
	IN 53-78	1	1	1	0	0	
	IN 53-78	2	19	5	11	17	
	IN 107-107	1	1	0	0	0	
	IN 107-107	2	20	8	5	1	
Spontaneous tumor pct: 2%	in ctrl. - Total	-	2	1	0	1	
LIVER X 2	(LIO) IN 92-106	1	0	1	0	0	0.606 0.653 1.000
HEPATOCELLULAR CARCINOMA	(789) IN 92-106	2	48	29	27	17	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	1	0	0	
LIVER X 2	(LIO) IN 92-106	1	1	1	0	0	0.847 0.781 1.000
HAEMANGIOSARCOMA	(933) IN 92-106	2	47	29	27	17	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	1	0	0	

LUNGS X 2	(LLO	)	IN 53-78	1	0	0	0	2	0.379 0.378 0.995
PULMONARY ADENOMA	(091	)	IN 53-78	2	21	7	11	15	
			IN 79-91	1	2	0	2	1	
			IN 79-91	2	13	5	10	13	
			IN 92-106	1	6	6	3	2	
			IN 92-106	2	42	24	24	15	
			IN 107-107	1	4	2	2	0	
			IN 107-107	2	18	6	3	1	
Spontaneous tumor pct: 11% in ctrl. - Total				-	12	8	7	5	
LUNGS X 2	(LLO	)	IN 53-78	1	1	0	0	0	0.646 0.659 1.000
PULMONARY CARCINOMA	(290	)	IN 53-78	2	20	6	11	17	
			IN 92-106	1	0	1	2	1	
			IN 92-106	2	47	28	25	16	
			IN 107-107	1	2	0	0	0	
			IN 107-107	2	20	8	5	1	
			FA 76	1	0	1	0	0	
			FA 76	2	87	44	48	34	
			FA 91	1	1	0	0	0	
			FA 91	2	71	38	33	20	
			FA 94	1	1	0	0	0	
			FA 94	2	67	35	31	16	
			FA 95	1	0	1	0	0	
			FA 95	2	66	34	31	14	
Spontaneous tumor pct: 5% in ctrl. - Total				-	5	3	2	1	
L N	(LM	)	IN 53-78	1	1	0	0	0	0.864 0.849 1.000
	(000	)	IN 53-78	2	19	7	11	17	
			IN 79-91	1	0	0	1	0	
			IN 79-91	2	15	5	10	14	
			IN 92-106	1	1	0	0	0	
			IN 92-106	2	46	30	27	17	
Spontaneous tumor pct: 2% in ctrl. - Total				-	2	0	1	0	
L N	(LS	)	IN 0-52	1	0	0	0	1	0.126 0.114 1.000
	(000	)	IN 0-52	2	4	5	0	4	
			IN 92-106	1	0	0	1	0	
			IN 92-106	2	48	30	25	17	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	1	1	
L N	(LT	)	IN 0-52	1	0	0	0	1	0.357 0.090 1.000
	(000	)	IN 0-52	2	4	5	0	4	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	0	1	
MAMMARY A. CA/CR	(MA	)	IN 53-78	1	1	0	0	2	0.002 0.000 0.858
CARCINOMA	(429	)	IN 53-78	2	20	7	11	15	
			IN 92-106	1	0	0	3	1	
			IN 92-106	2	48	30	23	16	
			IN 107-107	1	1	0	1	0	
			IN 107-107	2	21	8	4	1	
			FA 46	1	0	0	0	1	
			FA 46	2	108	52	55	50	
			FA 88	1	0	0	1	1	
			FA 88	2	78	39	37	21	
			FA 102	1	0	0	1	0	
			FA 102	2	57	29	23	9	
Spontaneous tumor pct: 2% in ctrl. - Total				-	2	0	6	5	

MAMMARY A. CA/CR	(MA	) IN 79-91	1	0	0	2	0	0.011	0.005	0.967
ADENOACANTHOMA	(531	) IN 79-91	2	15	4	10	11			
		IN 92-106	1	0	0	3	1			
		IN 92-106	2	48	29	24	16			
		IN 107-107	1	1	0	0	0			
		IN 107-107	2	21	8	5	1			
	FA 82	1	0	0	0	1				
	FA 82	2	83	41	43	29				
	FA 85	1	0	0	0	1				
	FA 85	2	83	40	40	25				
	FA 86	1	0	1	0	0				
	FA 86	2	81	39	39	23				
	FA 88	1	0	0	0	1				
	FA 88	2	78	39	38	21				
	FA 100	1	0	1	0	0				
	FA 100	2	80	31	25	11				
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	2	5	4			
MAMMARY A. CA/CR	(MA	) IN 92-106	1	0	1	0	0	0.606	0.653	1.000
FIBROADENOMA	(567	) IN 92-106	2	48	29	27	17			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0			
MAMMARY A. CA/CR	(MA	) FA 72	1	0	0	0	1	0.024	0.010	1.000
CARCINOSARCOMA	(844	) FA 72	2	94	47	50	39			
	FA 74	1	0	0	0	1				
	FA 74	2	91	46	50	36				
	FA 86	1	0	0	1	0				
	FA 86	2	81	40	38	23				
	FA 100	1	0	1	0	0				
	FA 100	2	60	31	25	11				
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	1	2	(Exact	P<0.025)	
MAMMARY A. CA/CR	(MA	) IN 79-91	1	0	0	0	1	0.304	0.073	1.000
ADENOACANTHOMA	(864	) IN 79-91	2	15	5	12	13			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
MUSCULO-SKELETAL	(MS	) IN 92-106	1	0	1	0	1	0.035	0.010	1.000
OSTEOSARCOMA	(374	) IN 92-106	2	48	29	27	16			
	FA 60	1	0	0	0	1				
	FA 60	2	104	49	54	46				
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	2			
MUSCULO-SKELETAL	(MS	) FA 99	1	0	0	0	1	0.097	0.002	1.000
SARCOMA	(812	) FA 99	2	61	32	27	12			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
MESENTERY	(MT	) IN 53-78	1	1	0	0	0	1.000	0.814	1.000
	(000	) IN 53-78	2	19	7	11	17			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
OVARIES+OVIDUCTS	(OA	) IN 53-78	1	1	0	1	0	0.868	0.876	1.000
	(000	) IN 53-78	2	19	7	9	17			
	IN 79-91	1	1	0	1	0				
	IN 79-91	2	13	5	10	14				
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	2	0			
OVARIES+OVIDUCTS	(OA	) IN 53-78	1	1	0	0	0	0.664	0.628	1.000
ADENOMA	(725	) IN 53-78	2	19	7	10	17			

		IN 79-91	1	1	0	0	0	
		IN 79-91	2	13	5	11	14	
		IN 92-106	1	1	0	0	1	
		IN 92-106	2	47	30	27	16	
Spontaneous tumor pct: 3%	in ctrl.	- Total	-	3	0	0	1	
OVARIES+OVIDUCTS	(OA	) IN 92-106	1	1	0	0	0	1.000 0.802 1.000
GRANULOSA/THECA CELL TUMO	(837	) IN 92-106	2	47	30	27	17	
		IN 107-107	1	1	0	0	0	
		IN 107-107	2	21	8	5	1	
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2	0	0	0	
OVARIES+OVIDUCTS	(OA	) IN 92-106	1	2	0	0	0	1.000 0.865 1.000
LUTEOMA	(938	) IN 92-106	2	46	30	27	17	
		IN 107-107	1	1	0	0	0	
		IN 107-107	2	21	8	5	1	
Spontaneous tumor pct: 3%	in ctrl.	- Total	-	3	0	0	0	
OPTIC NERVES L&R	(OP	) IN 92-106	1	1	0	0	1	0.271 0.178 1.000
	(000	) IN 92-106	2	46	30	27	15	
		IN 107-107	1	1	0	0	0	
		IN 107-107	2	20	8	5	1	
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2	0	0	1	
PANCREAS	(PA	) IN 53-78	1	1	0	0	0	1.000 0.814 1.000
	(000	) IN 53-78	2	19	7	11	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	0	0	0	
PANCREAS	(PA	) IN 79-91	1	0	0	0	1	0.304 0.073 1.000
ISLET CELL ADENOMA	(503	) IN 79-91	2	15	5	12	13	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	0	1	
PANCREAS	(PA	) IN 92-106	1	0	0	0	1	0.139 0.009 1.000
ISLET CELL CARCINOMA	(771	) IN 92-106	2	48	30	27	16	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	0	1	
PARATHYROIDES	(PD	) IN 0-52	1	1	0	0	2	0.152 0.146 0.872
	(000	) IN 0-52	2	2	5	0	2	
		IN 53-78	1	8	1	2	6	
		IN 53-78	2	5	5	7	5	
		IN 79-91	1	3	1	0	6	
		IN 79-91	2	9	3	12	2	
		IN 92-106	1	7	8	3	1	
		IN 92-106	2	34	14	21	15	
		IN 107-107	1	2	1	2	0	
		IN 107-107	2	18	6	1	1	
Spontaneous tumor pct: 19%	in ctrl.	- Total	-	21	11	7	15	
PITUITARY	(PI	) IN 0-52	1	0	0	0	2	0.000 0.000 0.000
ADENOMA	(121	) IN 0-52	2	4	5	0	4	
		IN 53-78	1	0	0	3	4	
		IN 53-78	2	21	7	7	3	
		IN 79-91	1	0	1	3	3	
		IN 79-91	2	15	4	6	2	
		IN 92-106	1	1	4	6	4	
		IN 92-106	2	46	25	14	5	
		IN 107-107	1	2	1	4	1	
		IN 107-107	2	20	7	1	0	

FA 59	1	0	0	0	1
FA 59	2	105	49	54	47
FA 60	1	0	0	0	1
FA 60	2	104	49	54	46
FA 61	1	0	0	0	1
FA 61	2	102	49	54	44
FA 64	1	0	0	1	0
FA 64	2	99	48	53	44
FA 70	1	0	0	0	1
FA 70	2	96	47	51	41
FA 71	1	0	0	0	1
FA 71	2	94	47	50	40
FA 73	1	0	0	0	1
FA 73	2	94	46	50	38
FA 74	1	0	0	0	1
FA 74	2	91	46	50	36
FA 75	1	0	0	0	1
FA 75	2	88	45	48	34
FA 76	1	0	0	0	1
FA 76	2	87	45	48	33
FA 78	1	0	0	0	1
FA 78	2	85	43	45	32
FA 80	1	0	0	0	1
FA 80	2	83	43	44	31
FA 81	1	0	0	0	1
FA 81	2	83	42	43	30
FA 82	1	0	0	0	2
FA 82	2	83	41	43	28
FA 84	1	0	0	0	1
FA 84	2	83	41	40	26
FA 85	1	0	0	1	2
FA 85	2	83	40	39	24
FA 88	1	0	0	1	1
FA 88	2	78	39	37	21
FA 91	1	0	0	1	1
FA 91	2	72	38	32	19
FA 93	1	0	0	1	2
FA 93	2	68	37	31	16
FA 94	1	0	0	0	1
FA 94	2	68	35	31	15
FA 95	1	0	0	1	1
FA 95	2	66	35	30	13
FA 97	1	0	1	0	0
FA 97	2	64	32	29	13
FA 98	1	0	0	1	0
FA 98	2	63	32	28	13
FA 99	1	0	0	2	1
FA 99	2	61	32	25	12
FA 100	1	0	0	0	1
FA 100	2	60	32	25	10
FA 102	1	0	0	1	0
FA 102	2	57	29	23	9
FA 103	1	0	0	0	2
FA 103	2	57	29	22	7
FA 104	1	0	0	1	0
FA 104	2	54	27	20	7
FA 105	1	1	0	0	0
FA 105	2	53	25	20	7

Spontaneous tumor pct: 4%	in ctrl.	- Total	-	4	7	27	41	
PITUITARY	(PI	) IN 92-106	1	0	0	1	0	0.072 0.029 1.000
CARCINOMA	(272	) IN 92-106	2	48	30	26	17	
	FA 91	1	0	0	0	1		
	FA 91	2	72	38	33	19		
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	1	1	
PITUITARY	(PI	) IN 92-106	1	0	0	0	1	0.163 0.036 1.000
ADENOMA OF PARS INTERMEDI	(888	) IN 92-106	2	48	30	27	16	
	IN 107-107	1	1	0	0	0		
	IN 107-107	2	21	8	5	1		
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	0	0	1	
PITUITARY	(PI	) IN 53-78	1	1	0	0	0	1.000 0.810 1.000
CRANIOPHARYNGIOMA	(912	) IN 53-78	2	20	7	11	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	0	0	0	
SALIVARY GLANDS	(SA	) IN 53-78	1	1	0	0	0	1.000 0.814 1.000
	(000	) IN 53-78	2	19	7	11	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	0	0	0	
SPINAL C.CERV	(SC0	) IN 0-52	1	1	0	0	0	1.000 0.840 1.000
	(000	) IN 0-52	2	2	5	0	6	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	1	0	0	0	
SKIN OTHER	(SK0	) IN 92-106	1	0	1	0	0	0.603 0.654 1.000
	(000	) IN 92-106	2	48	28	27	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	0	
SKIN OTHER	(SK0	) IN 107-107	1	0	0	1	0	0.166 0.129 1.000
SQUAMOUS CELL CARCINOMA	(043	) IN 107-107	2	22	8	4	1	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	1	0	
SKIN OTHER	(SK0	) IN 92-106	1	1	0	1	0	0.603 0.676 1.000
SARCOMA	(162	) IN 92-106	2	47	29	25	17	
	FA 73	1	1	0	0	0		
	FA 73	2	93	45	50	39		
	FA 96	1	0	0	1	0		
	FA 96	2	64	32	29	13		
Spontaneous tumor pct: 2%	in ctrl.	- Total	-	2	0	2	0	
SKIN OTHER	(SK0	) FA 95	1	0	1	0	0	0.544 0.614 1.000
HAEMANGIOSARCOMA	(512	) FA 95	2	66	33	31	14	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	1	0	0	
SKIN OTHER	(SK0	) IN 79-91	1	0	0	0	1	0.304 0.073 1.000
PAPILLOMA	(583	) IN 79-91	2	15	5	12	13	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	0	1	
STOMACH X 2	(ST0	) IN 92-106	1	0	0	1	0	0.360 0.416 1.000
BILE DUCT CARCINOMA	(773	) IN 92-106	2	48	30	26	17	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	1	0	
THYROIDS	(TD	) IN 79-91	1	0	0	0	1	0.288 0.066 1.000
	(000	) IN 79-91	2	15	5	12	12	
Spontaneous tumor pct: <= 1%	in ctrl.	- Total	-	0	0	0	1	

TONGUE	(TO)	IN 0-52	1	0	0	0	1	0.357	0.090	1.000
	(000)	IN 0-52	2	4	5	0	4			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
TRACHEA	(TR)	IN 53-78	1	1	0	1	0	0.747	0.777	1.000
	(000)	IN 53-78	2	19	7	9	17			
		IN 79-91	1	0	0	1	0			
		IN 79-91	2	15	5	10	14			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	2	0			
THYMUS	(TY)	IN 53-78	1	0	0	1	1	0.283	0.261	1.000
	(000)	IN 53-78	2	21	7	9	15			
		IN 79-91	1	1	0	0	0			
		IN 79-91	2	13	5	12	14			
		IN 92-106	1	1	1	0	1			
		IN 92-106	2	46	28	27	15			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	1	1	2			
URINARY BLADDER	(UB)	IN 0-52	1	0	1	0	0	0.937	0.903	1.000
	(000)	IN 0-52	2	4	3	0	6			
		IN 92-106	1	2	1	0	0			
		IN 92-106	2	44	28	27	17			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	2	0	0			
UTERUS	(UT)	IN 53-78	1	0	1	0	3	0.010	0.007	0.413
STROMAL POLYP	(085)	IN 53-78	2	21	6	8	14			
		IN 79-91	1	2	1	5	3			
		IN 79-91	2	12	4	6	11			
		IN 92-106	1	8	3	6	6			
		IN 92-106	2	39	27	21	11			
		IN 107-107	1	2	2	2	1			
		IN 107-107	2	20	6	3	0			
		FA 67	1	0	0	1	0			
		FA 67	2	96	48	52	43			
		FA 70	1	0	0	1	0			
		FA 70	2	96	47	50	42			
		FA 74	1	0	0	1	0			
		FA 74	2	91	46	49	37			
		FA 83	1	0	0	1	0			
		FA 83	2	83	41	40	27			
		FA 90	1	1	0	0	0			
		FA 90	2	73	39	34	20			
		FA 105	1	1	0	0	0			
		FA 105	2	53	25	20	7			
Spontaneous tumor pct: 13% in ctrl. - Total			-	14	7	17	13			
UTERUS	(UT)	IN 53-78	1	1	0	0	0	1.000	0.869	1.000
HAEMANGIOMA	(116)	IN 53-78	2	20	7	11	17			
		IN 92-106	1	1	0	0	0			
		IN 92-106	2	47	30	27	17			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0			
UTERUS	(UT)	IN 53-78	1	0	0	0	1	0.303	0.071	1.000
ADENOMA	(198)	IN 53-78	2	21	7	11	16			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
UTERUS	(UT)	IN 79-91	1	0	0	0	1	0.489	0.463	1.000
LEIOMYOMA	(292)	IN 79-91	2	15	5	12	13			

			IN 92-106	1	1	1	0	0	
			IN 92-106	2	47	29	27	17	
			IN 107-107	1	2	0	0	0	
			IN 107-107	2	20	8	5	1	
Spontaneous tumor pct: 3% in ctrl. - Total					-	3	1	0	1
UTERUS	(UT	)	IN 53-78	1	0	0	1	0	0.404 0.413 1.000
LEIOMYOSARCOMA	(368	)	IN 53-78	2	21	6	10	16	
			IN 79-91	1	0	0	1	0	
			IN 79-91	2	13	5	11	14	
			IN 92-106	1	2	0	1	0	
			IN 92-106	2	46	29	26	17	
			FA 52	1	0	0	0	1	
			FA 52	2	106	50	55	49	
			FA 57	1	0	0	0	1	
			FA 57	2	106	49	54	48	
			FA 72	1	0	1	0	0	
			FA 72	2	94	46	50	40	
			FA 86	1	1	0	0	0	
			FA 86	2	80	40	39	23	
			FA 88	1	1	0	0	0	
			FA 88	2	77	39	38	22	
			FA 105	1	0	1	0	0	
			FA 105	2	54	24	20	7	
Spontaneous tumor pct: 4% in ctrl. - Total					-	4	2	3	2
UTERUS	(UT	)	IN 53-78	1	0	0	1	2	0.000 0.000 0.266
ADENOCARCINOMA	(435	)	IN 53-78	2	21	7	9	15	
			IN 79-91	1	0	0	3	2	
			IN 79-91	2	15	5	8	12	
			IN 92-106	1	0	2	4	5	
			IN 92-106	2	48	27	23	12	
			IN 107-107	1	0	1	0	0	
			IN 107-107	2	22	7	5	1	
			FA 77	1	0	0	1	0	
			FA 77	2	86	44	46	33	
			FA 83	1	0	0	1	0	
			FA 83	2	83	41	40	27	
			FA 105	1	0	1	0	0	
			FA 105	2	54	24	20	7	
Spontaneous tumor pct: <= 1% in ctrl. - Total					-	0	4	10	9
UTERUS	(UT	)	FA 84	1	0	1	0	0	0.132 0.076 1.000
SARCOMA	(442	)	FA 84	2	83	40	40	27	
			FA 87	1	0	0	0	1	
			FA 87	2	80	39	38	22	
Spontaneous tumor pct: <= 1% in ctrl. - Total					-	0	1	0	1
UTERUS	(UT	)	IN 92-106	1	1	0	0	0	1.000 0.883 1.000
HAEMANGIOSARCOMA	(646	)	IN 92-106	2	47	30	27	17	
			IN 107-107	1	2	0	0	0	
			IN 107-107	2	20	8	5	1	
			FA 85	1	1	0	0	0	
			FA 85	2	82	40	40	26	
Spontaneous tumor pct: 4% in ctrl. - Total					-	4	0	0	0
UTERUS	(UT	)	IN 92-106	1	1	0	0	0	1.000 0.757 1.000
GRANULAR CELL TUMOUR	(823	)	IN 92-106	2	47	30	27	17	

Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1	0	0	0	
UTERINE CERVIX	(UX	)	IN 53-78	1	0	1	0	0	0.229 0.201 1.000
	(000	)	IN 53-78	2	21	5	11	17	
			IN 79-91	1	0	0	0	1	
			IN 79-91	2	15	5	12	12	
			IN 92-106	1	2	0	1	1	
			IN 92-106	2	44	30	25	15	
Spontaneous tumor pct: 2% in ctrl. - Total				-	2	1	1	2	
UTERINE CERVIX	(UX	)	IN 53-78	1	1	0	0	0	0.898 0.886 1.000
STROMAL POLYP	(543	)	IN 53-78	2	20	6	11	17	
			IN 79-91	1	0	1	0	0	
			IN 79-91	2	15	4	12	13	
			IN 92-106	1	2	3	2	0	
			IN 92-106	2	43	27	24	16	
			IN 107-107	1	0	0	1	0	
			IN 107-107	2	22	8	4	1	
			FA 105	1	1	0	0	0	
			FA 105	2	52	25	20	7	
Spontaneous tumor pct: 4% in ctrl. - Total				-	4	4	3	0	
UTERINE CERVIX	(UX	)	IN 92-106	1	1	0	0	0	1.000 0.756 1.000
FIBROMA	(778	)	IN 92-106	2	45	30	26	16	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1	0	0	0	
UTERINE CERVIX	(UX	)	IN 107-107	1	1	0	0	0	1.000 0.690 1.000
LEIOMYOMA	(824	)	IN 107-107	2	21	8	5	1	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	1	0	0	0	
UTERINE CERVIX	(UX	)	IN 92-106	1	0	1	0	0	0.610 0.651 1.000
SQUAMOUS CELL CARCINOMA	(847	)	IN 92-106	2	46	29	26	16	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	0	0	
UTERINE CERVIX	(UX	)	IN 92-106	1	0	0	1	0	0.355 0.411 1.000
GRANULAR CELL TUMOUR	(865	)	IN 92-106	2	46	30	25	16	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	1	0	
UTERINE CERVIX	(UX	)	IN 0-52	1	0	1	0	0	0.698 0.791 1.000
ADENOCARCINOMA	(919	)	IN 0-52	2	4	4	0	6	
			IN 92-106	1	0	1	0	0	
			IN 92-106	2	46	29	26	16	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	2	0	0	
UTERINE CERVIX	(UX	)	FA 52	1	0	0	0	1	0.120 0.063 1.000
LEIOMYOSARCOMA	(921	)	FA 52	2	104	49	54	47	
			FA 105	1	0	1	0	0	
			FA 105	2	53	24	20	7	
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	0	1	
VAGINA	(VG	)	IN 53-78	1	1	1	0	1	0.472 0.461 1.000
	(000	)	IN 53-78	2	19	5	11	15	
			IN 79-91	1	0	0	0	1	
			IN 79-91	2	15	5	12	12	
			IN 92-106	1	1	2	0	0	
			IN 92-106	2	46	26	27	17	
			IN 107-107	1	0	1	0	0	
			IN 107-107	2	22	6	5	1	

Spontaneous tumor pct: 2% in ctrl. - Total - 2 4 0 2

Table 4c

Analysis of Carcinogenic Potential in Female Mouse
 Test of Dose-Response (Tumor) Positive Linear Trend
 Study No.

Run Date & Time: November 2, 1999 (10:03)

Source: C:\NG\mwmic3.dat

Note: Dose Levels Included: CTRL LOW MED HIGH (0 1 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 TIME TYPES STRATA	ROW NO.	2x2 CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
ADRENAL CTX L&R	(AD)	IN 79-91	1	1 0 0 0	1.000 0.770 0.808
	(000)	IN 79-91	2	13 3 7 6	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
ADRENAL CTX L&R	(AD)	IN 107-107	1	0 0 1 0	0.405 0.511 0.562
CORTICAL ADENOCARCINOMA	(497)	IN 107-107	2	22 19 11 16	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 1 0	
ABDOMINAL FAT	(AF)	IN 107-107	1	0 0 0 1	0.231 0.039 0.051
HAEMANGIOMA	(444)	IN 107-107	2	22 19 12 15	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 0 1	
ADRENAL MED L&R	(AM)	IN 79-91	1	1 0 0 0	1.000 0.770 0.808
	(000)	IN 79-91	2	13 3 7 6	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
ADRENAL MED L&R	(AM)	IN 107-107	1	0 0 1 0	0.405 0.511 0.562
PHAECHROMOCYTOMA	(883)	IN 107-107	2	22 19 11 16	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 1 0	
ADRENAL MED L&R	(AM)	IN 53-78	1	1 0 0 0	0.748 0.765 0.797
PHAECHROMOCYTOMA	(953)	IN 53-78	2	20 7 8 3	
		IN 79-91	1	0 1 0 0	
		IN 79-91	2	14 2 7 6	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 1 0 0	
AORTA	(AO)	IN 0-52	1	0 0 1 1	0.090 0.074 0.083
	(000)	IN 0-52	2	4 2 -1 2	
		IN 53-78	1	1 1 0 0	
		IN 53-78	2	19 5 8 3	
		IN 79-91	1	0 0 0 1	
		IN 79-91	2	15 3 7 4	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 1 1 2	
BRAIN X 3	(BNO)	FA 97	1	0 0 1 0	0.410 0.491 0.543
MENINGEAL SARCOMA	(552)	FA 97	2	64 41 35 37	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 1 0	
COLON	(CO)	IN 92-106	1	0 1 0 0	0.612 0.694 0.738
	(000)	IN 92-106	2	48 22 27 26	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 0 0	

COLON	(CO	)	IN 107-107	1	0	1	0	0	0.681	0.705	0.748
ADENOCARCINOMA	(546	)	IN 107-107	2	22	18	12	16			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	0	0			
DUODENUM	(DU	)	IN 0-52	1	0	0	0	2	0.052	0.026	0.032
	(000	)	IN 0-52	2	4	2	1	0			
			IN 92-106	1	0	1	0	0			
			IN 92-106	2	48	22	27	26			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	1	0	2			
FEMUR AND MARROW	(FM	)	IN 92-106	1	0	0	1	0	0.424	0.491	0.544
OSTEOMA	(459	)	IN 92-106	2	48	24	26	26			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	1	0			
GALL BLADDER	(GB	)	IN 0-52	1	0	1	0	2	0.167	0.152	0.162
	(000	)	IN 0-52	2	4	0	1	0			
			IN 53-78	1	1	0	1	0			
			IN 53-78	2	19	7	6	3			
			IN 79-91	1	1	0	1	1			
			IN 79-91	2	13	3	5	4			
			IN 92-106	1	1	1	2	0			
			IN 92-106	2	46	22	23	26			
Spontaneous tumor pct: 3% in ctrl. - Total				-	3	2	4	3			
HARDERIAN GLANDS	(HG	)	IN 92-106	1	0	0	0	2	0.009	0.002	0.003
CARCINOMA	(127	)	IN 92-106	2	48	24	26	24			
			IN 107-107	1	0	0	0	1			
			IN 107-107	2	22	19	12	15			
			FA 100	1	0	0	1	0			
			FA 100	2	60	40	31	35			
Spontaneous tumor pct: <= 1% in ctrl. - Total				-	0	0	1	3	(Asymptotic P<0.050)		
HARDERIAN GLANDS	(HG	)	IN 53-78	1	1	0	1	0	0.078	0.068	0.072
ADENOMA	(203	)	IN 53-78	2	20	7	7	3			
			IN 79-91	1	1	0	0	0			
			IN 79-91	2	14	3	7	6			
			IN 92-106	1	3	0	1	5			
			IN 92-106	2	45	24	26	21			
			IN 107-107	1	3	2	1	2			
			IN 107-107	2	19	17	11	14			
Spontaneous tumor pct: 7% in ctrl. - Total				-	8	2	3	7			
H'POIETIC TUMOUR	(HP	)	IN 53-78	1	1	0	0	0	0.115	0.110	0.113
MALIGNANT LYMPHOMA	(052	)	IN 53-78	2	13	7	6	2			
			IN 92-106	1	4	4	4	3			
			IN 92-106	2	42	20	20	20			
			IN 107-107	1	7	1	2	6			
			IN 107-107	2	15	18	10	10			
			FA 31	1	0	0	0	1			
			FA 31	2	108	54	54	52			
			FA 46	1	0	0	0	1			
			FA 46	2	108	54	54	51			
			FA 50	1	0	1	0	0			
			FA 50	2	106	53	54	51			
			FA 59	1	1	0	0	0			
			FA 59	2	104	52	53	51			
			FA 61	1	1	0	0	0			

FA 61	2	101	52	53	50
FA 64	1	0	0	1	0
FA 64	2	99	52	52	50
FA 70	1	1	0	0	0
FA 70	2	95	50	50	49
FA 73	1	1	0	1	0
FA 73	2	93	49	48	49
FA 74	1	2	0	0	1
FA 74	2	89	49	47	48
FA 76	1	1	0	0	0
FA 76	2	86	47	47	48
FA 79	1	0	1	1	0
FA 79	2	85	45	45	48
FA 80	1	0	1	0	0
FA 80	2	83	44	45	47
FA 85	1	1	0	0	0
FA 85	2	82	44	45	45
FA 86	1	0	0	0	1
FA 86	2	81	44	45	44
FA 87	1	1	0	0	0
FA 87	2	79	44	43	44
FA 89	1	0	0	0	1
FA 89	2	76	44	42	43
FA 90	1	0	1	1	0
FA 90	2	74	43	41	43
FA 91	1	1	0	0	0
FA 91	2	71	43	39	42
FA 92	1	1	0	0	0
FA 92	2	69	43	39	42
FA 95	1	0	0	0	1
FA 95	2	66	42	39	38
FA 96	1	0	0	1	0
FA 96	2	64	42	37	38
FA 99	1	0	0	0	1
FA 99	2	61	40	34	35
FA 100	1	0	0	1	0
FA 100	2	60	40	31	35
FA 101	1	1	0	0	0
FA 101	2	57	39	29	34
FA 102	1	0	0	0	1
FA 102	2	57	38	29	32
FA 105	1	0	0	1	0
FA 105	2	54	35	27	32

Spontaneous tumor pct: 22% in ctrl. - Total - 24 9 13 17

H'POIETIC TUMOUR	(HP	) IN 92-106	1	1	1	0	0
HISTIOCYTIC SARCOMA	(299	) IN 92-106	2	46	23	26	26
		IN 107-107	1	1	0	0	0
		IN 107-107	2	21	19	12	16
FA 60			1	1	0	0	0
FA 60			2	103	52	53	51
FA 68			1	0	0	1	0
FA 68			2	96	50	51	49
FA 79			1	1	0	0	0
FA 79			2	84	46	46	48
FA 89			1	1	0	0	0
FA 89			2	75	44	42	44
FA 99			1	0	0	1	0

0.973 0.954 0.958

	FA 99	2	61	40	33	36	
	FA 100	1	1	0	0	0	
	FA 100	2	59	40	32	35	
Spontaneous tumor pct: 5%	in ctrl. - Total	-	6	1	2	0	
H'POIETIC TUMOUR (HP)	FA 102	1	0	0	0	1	0.210 0.031 0.041
GRANULOCYTIC LEUKAEMIA (970)	FA 102	2	57	38	29	32	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	0	1	
ILEUM (IL)	IN 0-52	1	0	1	0	1	0.299 0.316 0.339
(000)	IN 0-52	2	4	0	1	2	
	IN 79-91	1	0	0	1	0	
	IN 79-91	2	15	3	5	6	
	IN 92-106	1	0	0	1	0	
	IN 92-106	2	48	24	25	26	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	1	2	1	
JEJUNUM (JE)	IN 53-78	1	1	0	0	0	0.645 0.717 0.745
(000)	IN 53-78	2	19	7	8	3	
	IN 92-106	1	0	1	1	0	
	IN 92-106	2	48	22	25	26	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	1	1	0	
L N (LB)	IN 107-107	1	0	0	1	0	0.397 0.511 0.562
(000)	IN 107-107	2	22	19	10	16	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	1	0	
L N (LC)	IN 53-78	1	1	0	0	0	0.238 0.210 0.228
(000)	IN 53-78	2	19	7	8	3	
	IN 79-91	1	0	0	3	0	
	IN 79-91	2	15	3	1	6	
	IN 92-106	1	0	0	0	1	
	IN 92-106	2	48	24	27	24	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	0	3	1	
LACHRYMAL GLANDS (LG)	IN 53-78	1	1	0	0	0	0.754 0.767 0.791
(000)	IN 53-78	2	19	7	8	3	
	IN 79-91	1	0	0	1	0	
	IN 79-91	2	15	3	5	6	
	IN 107-107	1	1	0	0	0	
	IN 107-107	2	20	19	12	16	
Spontaneous tumor pct: 2%	in ctrl. - Total	-	2	0	1	0	
LIVER X 2 (LIO)	IN 92-106	1	0	0	1	0	0.424 0.491 0.544
HEPATOCELLULAR ADENOMA (809)	IN 92-106	2	48	24	26	26	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	1	0	
LIVER X 2 (LIO)	IN 92-106	1	0	0	1	0	0.424 0.491 0.544
HEPATOCELLULAR CARCINOMA (789)	IN 92-106	2	48	24	26	26	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	0	1	0	
LIVER X 2 (LIO)	IN 92-106	1	1	0	0	1	0.295 0.259 0.284
HAEMANGIOSARCOMA (933)	IN 92-106	2	47	24	27	25	
	FA 86	1	0	0	1	0	
	FA 86	2	81	44	44	45	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	0	1	1	
LUNGS X 2 (LLO)	IN 79-91	1	2	1	0	0	0.524 0.527 0.538

PULMONARY ADENOMA	(091	) IN 79-91	2	13	2	7	6	
		IN 92-106	1	6	1	2	3	
		IN 92-106	2	42	23	25	23	
		IN 107-107	1	4	2	0	3	
		IN 107-107	2	18	17	12	13	
Spontaneous tumor pct: 11%		in ctrl. - Total	-	12	4	2	6	
LUNGS X 2	(LLO	) IN 53-78	1	1	0	0	1	0.051 0.040 0.044
PULMONARY CARCINOMA	(290	) IN 53-78	2	20	7	8	2	
		IN 79-91	1	0	0	0	1	
		IN 79-91	2	14	3	7	5	
		IN 92-106	1	0	1	0	3	
		IN 92-106	2	47	23	27	23	
		IN 107-107	1	2	2	0	1	
		IN 107-107	2	20	17	12	15	
		FA 91	1	1	0	0	0	
		FA 91	2	71	43	39	42	
		FA 94	1	1	0	0	0	
		FA 94	2	67	42	39	41	
Spontaneous tumor pct: 5%		in ctrl. - Total	-	5	3	0	6	
L N	(LM	) IN 53-78	1	1	0	0	0	0.129 0.076 0.087
	(000	) IN 53-78	2	19	7	8	3	
		IN 92-106	1	1	0	0	2	
		IN 92-106	2	46	24	27	22	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	0	2	
L N	(LT	) IN 92-106	1	0	0	0	1	0.201 0.028 0.038
	(000	) IN 92-106	2	48	24	27	24	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
MAMMARY A. CA/CR	(MA	) IN 53-78	1	1	0	0	0	0.395 0.375 0.402
CARCINOMA	(429	) IN 53-78	2	20	7	8	3	
		IN 92-106	1	0	0	0	1	
		IN 92-106	2	48	24	27	25	
		IN 107-107	1	1	0	1	0	
		IN 107-107	2	21	19	11	16	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	1	1	
MAMMARY A. CA/CR	(MA	) IN 107-107	1	1	0	0	0	1.000 0.787 0.822
ADENOACANTHOMA	(531	) IN 107-107	2	21	19	12	16	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
MAMMARY A. CA/CR	(MA	) IN 92-106	1	0	1	2	0	0.542 0.606 0.635
ADENOACANTHOMA	(864	) IN 92-106	2	48	23	25	26	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	2	0	
MUSCULO-SKELETAL	(MS	) IN 92-106	1	0	0	0	1	0.208 0.031 0.041
OSTEOMA	(622	) IN 92-106	2	48	24	27	25	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
MUSCULO-SKELETAL	(MS	) IN 107-107	1	0	0	1	0	0.405 0.511 0.562
SARCOMA	(812	) IN 107-107	2	22	19	11	16	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
MESENTERY	(MT	) IN 53-78	1	1	0	0	0	1.000 0.722 0.780
	(000	) IN 53-78	2	19	7	8	3	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	

OVARIES+OVIDUCTS	(OA	) IN 53-78	1	1	0	0	0	1.000 0.827 0.853
	(000	) IN 53-78	2	19	7	8	3	
		IN 79-91	1	1	0	0	0	
		IN 79-91	2	13	3	7	6	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	0	0	
OVARIES+OVIDUCTS	(OA	) IN 53-78	1	1	0	0	0	0.769 0.768 0.782
ADENOMA	(725	) IN 53-78	2	19	7	8	3	
		IN 79-91	1	1	0	0	0	
		IN 79-91	2	13	3	7	6	
		IN 92-106	1	1	3	1	1	
		IN 92-106	2	47	21	26	25	
		IN 107-107	1	0	1	0	0	
		IN 107-107	2	22	18	12	16	
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3	4	1	1	
OVARIES+OVIDUCTS	(OA	) IN 92-106	1	1	0	1	0	0.519 0.549 0.570
GRANULOSA/THECA CELL TUMO	(837	) IN 92-106	2	47	23	26	26	
		IN 107-107	1	1	0	1	1	
		IN 107-107	2	21	19	11	15	
		FA 96	1	0	1	0	0	
		FA 96	2	64	41	38	38	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	1	2	1	
OVARIES+OVIDUCTS	(OA	) IN 92-106	1	2	0	0	0	0.712 0.687 0.708
LUTEOMA	(938	) IN 92-106	2	46	24	27	26	
		IN 107-107	1	1	1	0	1	
		IN 107-107	2	21	18	12	15	
Spontaneous tumor pct: 3%		in ctrl. - Total	-	3	1	0	1	
OPTIC NERVES L&R	(OP	) IN 53-78	1	0	1	0	0	0.804 0.822 0.836
	(000	) IN 53-78	2	21	5	8	3	
		IN 79-91	1	0	0	1	0	
		IN 79-91	2	15	3	5	6	
		IN 92-106	1	1	1	1	0	
		IN 92-106	2	46	22	25	26	
		IN 107-107	1	1	0	0	0	
		IN 107-107	2	20	19	12	16	
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	2	2	0	
PANCREAS	(PA	) IN 53-78	1	1	1	0	0	0.714 0.720 0.762
	(000	) IN 53-78	2	19	5	8	3	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	1	0	0	
PARATHYROIDS	(PD	) IN 0-52	1	1	1	0	1	0.839 0.834 0.840
	(000	) IN 0-52	2	2	0	1	2	
		IN 53-78	1	8	1	3	0	
		IN 53-78	2	5	5	2	3	
		IN 79-91	1	3	0	1	2	
		IN 79-91	2	9	3	5	2	
		IN 92-106	1	7	3	6	2	
		IN 92-106	2	34	18	15	22	
		IN 107-107	1	2	1	2	1	
		IN 107-107	2	18	17	8	14	
Spontaneous tumor pct: 19%		in ctrl. - Total	-	21	6	12	6	
PITUITARY	(PI	) IN 92-106	1	1	0	0	0	0.996 0.951 0.956

ADENOMA	(121	) IN 92-106	2	46	24	27	26	
		IN 107-107	1	2	1	0	0	
		IN 107-107	2	20	18	12	16	
		FA 105	1	1	0	0	0	
		FA 105	2	53	35	28	32	
Spontaneous tumor pct: 4%		in ctrl. - Total	-	4	1	0	0	
PITUITARY	(PI	) IN 107-107	1	1	0	0	0	1.000 0.787 0.822
ADENOMA OF PARS INTERMEDI	(888	) IN 107-107	2	21	19	12	16	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
PITUITARY	(PI	) IN 53-78	1	1	0	0	0	1.000 0.719 0.778
CRANIOPHARYNGIOMA	(912	) IN 53-78	2	20	7	8	3	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
PITUITARY	(PI	) FA 97	1	0	0	1	0	0.410 0.491 0.543
MENINGIOMA	(966	) FA 97	2	64	41	35	37	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
RECTUM	(RE	) IN 0-52	1	0	0	0	1	0.300 0.067 0.083
	(000	) IN 0-52	2	4	2	1	2	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
SALIVARY GLANDS	(SA	) IN 53-78	1	1	0	0	0	1.000 0.722 0.780
	(000	) IN 53-78	2	19	7	8	3	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
SPINAL C. CERV	(SC0	) IN 0-52	1	1	0	0	0	1.000 0.837 0.863
	(000	) IN 0-52	2	2	2	1	4	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	1	0	0	0	
SPINAL C. THOR	(SC2	) IN 92-106	1	0	0	1	0	0.419 0.491 0.543
	(000	) IN 92-106	2	48	24	25	26	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
SKIN OTHER	(SK0	) IN 92-106	1	0	0	1	0	0.419 0.491 0.543
	(000	) IN 92-106	2	48	24	25	26	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	1	0	
SKIN OTHER	(SK0	) IN 92-106	1	1	0	0	0	1.000 0.858 0.878
SARCOMA	(162	) IN 92-106	2	47	24	26	26	
	FA 73	1	1	0	0	0		
	FA 73	2	93	49	48	49		
Spontaneous tumor pct: 2%		in ctrl. - Total	-	2	0	0	0	
SKIN OTHER	(SK0	) FA 101	1	0	0	0	1	0.212 0.032 0.042
BASAL CELL CARCINOMA	(381	) FA 101	2	58	39	29	33	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	0	0	1	
SKIN OTHER	(SK0	) IN 92-106	1	0	0	1	0	0.504 0.634 0.668
KERATOACANTHOMA	(410	) IN 92-106	2	48	23	25	26	
	FA 104	1	0	1	0	0		
	FA 104	2	54	36	29	32		
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	1	0	
SKIN OTHER	(SK0	) FA 104	1	0	1	0	0	0.644 0.693 0.737
BASAL CELL TUMOUR	(965	) FA 104	2	54	36	29	32	
Spontaneous tumor pct: <= 1%		in ctrl. - Total	-	0	1	0	0	

SKIN OTHER	(SKO)	IN 92-106	1	0	0	1	0	0.419	0.491	0.543
LIPOSARCOMA	(967)	IN 92-106	2	48	24	25	26			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
SKIN OTHER	(SKO)	IN 107-107	1	0	0	1	0	0.405	0.511	0.562
BASAL CELL PAPILLOMA	(968)	IN 107-107	2	22	19	11	16			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
SPLEEN	(SP)	IN 79-91	1	0	0	1	0	0.419	0.469	0.522
HAEMANGIOSARCOMA	(340)	IN 79-91	2	15	3	6	6			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
TRACHEA	(TR)	IN 53-78	1	1	0	0	0	1.000	0.722	0.780
	(000)	IN 53-78	2	19	7	8	3			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
THYMUS	(TY)	IN 79-91	1	1	0	0	0	1.000	0.857	0.877
	(000)	IN 79-91	2	13	3	7	6			
		IN 92-106	1	1	0	0	0			
		IN 92-106	2	46	24	27	26			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0			
URINARY BLADDER	(UB)	IN 53-78	1	0	1	0	1	0.036	0.018	0.021
	(000)	IN 53-78	2	21	5	8	1			
		IN 92-106	1	2	0	0	2			
		IN 92-106	2	44	24	27	22			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	1	0	3			
UTERUS	(UT)	IN 53-78	1	0	0	0	1	0.166	0.160	0.166
STROMAL POLYP	(085)	IN 53-78	2	21	6	7	2			
		IN 79-91	1	2	0	0	2			
		IN 79-91	2	12	3	7	4			
		IN 92-106	1	8	1	5	4			
		IN 92-106	2	39	23	22	22			
		IN 107-107	1	2	2	6	3			
		IN 107-107	2	20	17	6	13			
		FA 57	1	0	1	0	0			
		FA 57	2	106	52	53	51			
		FA 71	1	0	0	1	0			
		FA 71	2	94	49	49	49			
		FA 90	1	1	0	0	0			
		FA 90	2	73	44	42	43			
		FA 105	1	1	0	0	0			
		FA 105	2	53	35	28	32			
Spontaneous tumor pct: 13% in ctrl. - Total			-	14	4	12	10			
UTERUS	(UT)	IN 53-78	1	1	0	0	0	1.000	0.832	0.857
HAEMANGIOMA	(116)	IN 53-78	2	20	7	8	3			
		IN 92-106	1	1	0	0	0			
		IN 92-106	2	47	24	27	26			
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0			
UTERUS	(UT)	IN 92-106	1	0	0	1	0	0.424	0.491	0.544
ADENOMA	(198)	IN 92-106	2	48	24	26	26			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
UTERUS	(UT)	IN 92-106	1	1	1	1	0	0.936	0.919	0.927

LEIOMYOMA	(292	)	IN 92-106	2	47	23	26	26	
			IN 107-107	1	2	1	0	0	
			IN 107-107	2	20	18	12	16	
Spontaneous tumor pct: 3%			in ctrl. - Total	-	3	2	1	0	
UTERUS	(UT	)	IN 92-106	1	2	0	2	0	0.923 0.912 0.920
LEIOMYOSARCOMA	(368	)	IN 92-106	2	46	23	25	26	
			FA 86	1	1	0	0	0	
			FA 86	2	80	44	45	45	
			FA 88	1	1	0	0	0	
			FA 88	2	77	44	43	44	
			FA 96	1	0	1	0	0	
			FA 96	2	64	41	38	38	
Spontaneous tumor pct: 4%			in ctrl. - Total	-	4	1	2	0	
UTERUS	(UT	)	FA 100	1	0	0	1	0	0.401 0.490 0.543
ADENOCARCINOMA	(435	)	FA 100	2	60	40	31	35	
Spontaneous tumor pct: <= 1%			in ctrl. - Total	-	0	0	1	0	
UTERUS	(UT	)	FA 105	1	0	1	0	0	0.637 0.694 0.738
SARCOMA	(442	)	FA 105	2	54	34	28	32	
Spontaneous tumor pct: <= 1%			in ctrl. - Total	-	0	1	0	0	
UTERUS	(UT	)	IN 92-106	1	1	0	1	0	0.927 0.917 0.924
HAEMANGIOSARCOMA	(646	)	IN 92-106	2	47	24	26	26	
			IN 107-107	1	2	1	0	0	
			IN 107-107	2	20	18	12	16	
			FA 85	1	1	0	0	0	
			FA 85	2	82	44	45	45	
			FA 90	1	0	0	1	0	
			FA 90	2	74	44	41	43	
Spontaneous tumor pct: 4%			in ctrl. - Total	-	4	1	2	0	
UTERUS	(UT	)	IN 92-106	1	1	0	0	0	1.000 0.779 0.816
GRANULAR CELL TUMOUR	(823	)	IN 92-106	2	47	24	27	26	
Spontaneous tumor pct: <= 1%			in ctrl. - Total	-	1	0	0	0	
UTERINE CERVIX	(UX	)	IN 53-78	1	0	0	1	0	0.209 0.183 0.199
	(000	)	IN 53-78	2	21	7	6	3	
			IN 92-106	1	2	0	0	2	
			IN 92-106	2	44	24	27	22	
			IN 107-107	1	0	1	0	0	
			IN 107-107	2	22	17	12	16	
Spontaneous tumor pct: 2%			in ctrl. - Total	-	2	1	1	2	
UTERINE CERVIX	(UX	)	IN 53-78	1	1	0	0	0	0.762 0.766 0.778
STROMAL POLYP	(543	)	IN 53-78	2	20	6	6	3	
			IN 92-106	1	2	1	1	0	
			IN 92-106	2	43	23	26	24	
			IN 107-107	1	0	1	1	1	
			IN 107-107	2	22	17	11	15	
			FA 57	1	0	1	0	0	
			FA 57	2	104	51	52	49	
			FA 68	1	0	0	1	0	
			FA 68	2	94	49	51	47	
			FA 105	1	1	0	0	0	
			FA 105	2	52	34	28	31	
Spontaneous tumor pct: 4%			in ctrl. - Total	-	4	3	3	1	

UTERINE CERVIX	(UX	) IN 92-106	1	1	1	0	0	0.857 0.814 0.839
FIBROMA	(778	) IN 92-106	2	45	23	27	24	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	0	0	
UTERINE CERVIX	(UX	) IN 107-107	1	1	0	0	0	1.000 0.788 0.823
LEIOMYOMA	(824	) IN 107-107	2	21	18	12	16	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
UTERINE CERVIX	(UX	) IN 92-106	1	0	0	1	0	0.421 0.484 0.537
GRANULAR CELL TUMOUR	(969	) IN 92-106	2	46	24	26	24	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0	
VAGINA	(VG	) IN 0-52	1	0	0	1	0	0.399 0.433 0.457
	(000	) IN 0-52	2	4	2	-1	4	
		IN 53-78	1	1	0	0	0	
		IN 53-78	2	19	7	8	3	
		IN 92-106	1	1	0	0	1	
		IN 92-106	2	46	24	27	24	
		IN 107-107	1	0	0	1	0	
		IN 107-107	2	22	19	10	16	
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	2	1	

Table 4d

Analysis of Carcinogenic Potential in Female Rat
 Test of Dose-Response (Tumor) Positive Linear Trend
 Study No.

Run Date & Time: September 14, 1999 (13:47)

Source: C:\NG\rat234.dat

Note: Dose Levels Included: CTRL LOW MED HIGH (0 0.303 3.03 10.1)
 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.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
CEREBRUM	(0101)	IN 92-108	1	1 0 0 0	1.000 0.774 0.810
MENINGIOMA	(010105)	IN 92-108	2	44 36 33 32	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
CEREBRUM	(0101)	IN 92-108	1	1 0 0 0	1.000 0.774 0.810
GRANULAR CELL TUMOR	(010107)	IN 92-108	2	44 36 33 32	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 82	1	1 0 0 0	1.000 0.755 0.794
HEMANGIOSARCOMA	(090015)	FA 82	2	94 49 51 46	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 53	1	0 1 0 0	0.849 0.825 0.847
HISTIOCYTIC SARCOMATOUS I	(090020)	FA 53	2	104 53 52 54	
		FA 91	1	1 0 0 0	
		FA 91	2	81 45 43 44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 1 0 0	
STOMACH	(1500)	FA 91	1	1 0 0 0	1.000 0.759 0.797
HISTIOCYTIC SARCOMATOUS I	(150014)	FA 91	2	81 45 43 44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
DUODENUM	(1601)	IN 109-110	1	1 0 0 0	1.000 0.728 0.770
FIBROMA	(160107)	IN 109-110	2	35 9 10 12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LIVER	(1800)	IN 92-108	1	0 1 1 5	0.001 0.000 0.000
HEPATOCELLULAR ADENOMA	(180004)	IN 92-108	2	45 35 32 27	
		IN 109-110	1	1 0 0 1	
		IN 109-110	2	35 9 10 11	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 1 1 6	
					(Exact P<0.025)
LIVER	(1800)	IN 92-108	1	0 0 1 1	0.146 0.098 0.115
HEPATOCELLULAR CARCINOMA	(180021)	IN 92-108	2	45 36 32 31	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 1 1	
PANCREAS	(2000)	IN 92-108	1	1 0 0 1	0.410 0.374 0.403
ISLET CELL ADENOMA	(200003)	IN 92-108	2	44 36 33 31	
		IN 109-110	1	0 1 0 0	
		IN 109-110	2	36 8 10 12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 1 0 1	
KIDNEYS	(2100)	FA 91	1	1 0 0 0	1.000 0.759 0.797

HISTIOCYTIC SARCOMATOUS I (210018)	FA 91	2	81	45	43	44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0
KIDNEYS	(2100) IN 79-91	1	0	1	0	0	0.531 0.704 0.754
HEMANGIOMA	(210019) IN 79-91	2	15	4	8	4	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0
URETERS	(2200) IN 79-91	1	1	0	0	0	1.000 0.735 0.782
HISTIOCYTIC SARCOMATOUS I (220003)	IN 79-91	2	14	5	8	4	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0
OVARIES	(3200) IN 79-91	1	0	0	0	1	0.125 0.007 0.010
TUBULOSTROMAL ADENOMA	(320009) IN 79-91	2	15	5	8	3	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1
OVARIES	(3200) IN 109-110	1	0	1	0	0	0.462 0.701 0.745
BENIGN GRANULOSA/THECA CE (320013)	IN 109-110	2	36	8	10	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0
OVARIES	(3200) IN 53-78	1	0	1	0	0	0.578 0.750 0.784
MALIGNANT GRANULOSA/THECA (320016)	IN 53-78	2	8	3	1	6	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0
OVIDUCT	(3300) FA 91	1	1	0	0	0	1.000 0.759 0.797
HISTIOCYTIC SARCOMATOUS I (330002)	FA 91	2	81	45	43	44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0
UTERUS (HORN)	(3400) IN 79-91	1	1	0	0	0	0.999 0.982 0.984
ADENOCARCINOMA	(340001) IN 79-91	2	13	4	8	4	
	IN 92-108	1	1	0	0	0	
	IN 92-108	2	41	36	33	32	
	IN 109-110	1	3	0	0	0	
	IN 109-110	2	33	9	10	12	
	FA 84	1	0	1	0	0	
	FA 84	2	94	47	50	45	
	FA 87	1	1	0	0	0	
	FA 87	2	84	45	45	44	
	FA 106	1	1	0	0	0	
	FA 106	2	68	34	36	38	
	FA 107	1	1	0	0	0	
	FA 107	2	57	25	26	28	
	FA 108	1	1	0	0	0	
	FA 108	2	49	19	20	22	
Spontaneous tumor pct: 8% in ctrl. - Total			-	9	1	0	0
UTERUS (HORN)	(3400) FA 69	1	1	0	0	0	1.000 0.755 0.794
FIBROMA	(340002) FA 69	2	100	53	51	51	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0
UTERUS (HORN)	(3400) IN 53-78	1	0	0	0	1	0.997 0.994 0.994
ENDOMETRIAL STROMAL POLYP (340005)	IN 53-78	2	8	4	1	5	
	IN 79-91	1	3	0	0	0	
	IN 79-91	2	12	5	8	4	
	IN 92-108	1	7	1	2	0	
	IN 92-108	2	38	35	31	32	
	IN 109-110	1	9	2	1	0	
	IN 109-110	2	27	7	9	12	
Spontaneous tumor pct: 17% in ctrl. - Total			-	19	3	3	1

UTERUS (HORN)	(3400)	IN 53-78	1	1	0	0	0	1.000	0.771	0.803
SCHWANNOMA	(340012)	IN 53-78	2	7	4	1	6			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
UTERUS (HORN)	(3400)	IN 92-108	1	0	2	0	0	0.802	0.862	0.877
ENDOMETRIAL ADENOMA	(340013)	IN 92-108	2	45	34	33	32			
		IN 109-110	1	0	1	0	0			
		IN 109-110	2	36	8	10	12			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	3	0	0			
UTERUS (HORN)	(3400)	FA 91	1	1	0	0	0	1.000	0.759	0.797
HISTIOCYTIC SARCOMATOUS I	(340017)	FA 91	2	81	45	43	44			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
CERVIX	(3401)	IN 79-91	1	1	0	0	0	1.000	0.903	0.915
STROMAL POLYP	(340108)	IN 79-91	2	14	5	8	4			
		IN 92-108	1	1	0	0	0			
		IN 92-108	2	44	36	33	32			
		IN 109-110	1	2	0	0	0			
		IN 109-110	2	34	9	10	12			
Spontaneous tumor pct: 4% in ctrl. - Total			-	4	0	0	0			
CERVIX	(3401)	FA 91	1	1	0	0	0	1.000	0.759	0.797
HISTIOCYTIC SARCOMATOUS I	(340111)	FA 91	2	81	45	43	44			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
CERVIX	(3401)	IN 92-108	1	0	0	1	0	0.445	0.494	0.544
FIBROSARCOMA	(340113)	IN 92-108	2	45	36	32	32			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
CLITORAL GLANDS	(3700)	IN 92-108	1	0	2	0	0	0.753	0.831	0.852
SQUAMOUS CELL CARCINOMA	(370002)	IN 92-108	2	45	34	33	32			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	2	0	0			
PITUITARY GLAND	(4100)	IN 53-78	1	1	0	0	0	0.978	0.977	0.977
ADENOMA OF PARS DISTALIS,	(410001)	IN 53-78	2	3	2	1	3			
		IN 79-91	1	1	2	2	0			
		IN 79-91	2	3	1	1	2			
		IN 92-108	1	21	11	13	14			
		IN 92-108	2	16	15	13	14			
		IN 109-110	1	30	4	4	4			
		IN 109-110	2	6	5	6	8			
	FA 60	1	0	0	0	1				
	FA 60	2	103	53	52	53				
	FA 63	1	0	0	0	1				
	FA 63	2	103	53	52	52				
	FA 67	1	1	0	0	0				
	FA 67	2	102	53	51	52				
	FA 69	1	1	1	0	0				
	FA 69	2	100	52	51	51				
	FA 76	1	1	1	0	0				
	FA 76	2	98	50	51	50				
	FA 77	1	0	0	0	1				
	FA 77	2	98	50	51	48				
	FA 78	1	1	0	0	0				
	FA 78	2	96	50	51	48				
	FA 80	1	1	0	0	0				

FA 80	2	95 50 51 47	
FA 81	1	0 0 0 1	
FA 81	2	95 49 51 46	
FA 82	1	0 0 1 0	
FA 82	2	95 49 50 46	
FA 84	1	3 0 1 0	
FA 84	2	91 48 49 45	
FA 85	1	2 1 1 1	
FA 85	2	88 46 47 44	
FA 86	1	3 1 0 0	
FA 86	2	85 45 47 44	
FA 87	1	1 0 1 0	
FA 87	2	84 45 44 44	
FA 89	1	1 0 0 0	
FA 89	2	82 45 44 44	
FA 90	1	0 0 1 0	
FA 90	2	82 45 43 44	
FA 92	1	2 0 1 0	
FA 92	2	79 45 42 44	
FA 93	1	0 2 1 0	
FA 93	2	79 43 41 44	
FA 94	1	1 0 0 0	
FA 94	2	78 43 41 44	
FA 95	1	0 0 0 1	
FA 95	2	78 43 41 43	
FA 97	1	0 0 0 1	
FA 97	2	78 43 41 42	
FA 98	1	1 1 0 0	
FA 98	2	77 42 41 42	
FA 99	1	0 1 0 1	
FA 99	2	76 41 41 41	
FA 100	1	1 1 2 0	
FA 100	2	75 39 39 40	
FA 101	1	1 0 2 0	
FA 101	2	73 39 37 40	
FA 102	1	0 4 0 1	
FA 102	2	73 35 37 39	
FA 104	1	1 1 0 0	
FA 104	2	72 34 37 38	
FA 105	1	0 0 1 0	
FA 105	2	70 34 36 38	
FA 107	1	1 0 0 0	
FA 107	2	57 25 26 28	
Spontaneous tumor pct: 69% in ctrl. - Total		-	76 31 31 27
PITUITARY GLAND	(4100) IN 109-110	1	1 0 0 0
CARCINOMA OF PARS DISTALI	(410009) IN 109-110	2	35 9 10 12
Spontaneous tumor pct: <= 1% in ctrl. - Total		-	1 0 0 0
THYROID GLAND	(4200) IN 79-91	1	0 1 0 0
C-CELL ADENOMA	(420001) IN 79-91	2	15 4 8 4
	IN 92-108	1	6 2 4 2
	IN 92-108	2	39 34 29 30
	IN 109-110	1	6 0 2 1
	IN 109-110	2	30 9 8 11
Spontaneous tumor pct: 11% in ctrl. - Total		-	12 3 6 3
THYROID GLAND	(4200) IN 79-91	1	1 0 0 0
			0.123 0.117 0.128

FOLLICULAR CELL ADENOMA	(420008)	IN 79-91	2	14	5	8	4	
		IN 92-108	1	0	1	2	0	
		IN 92-108	2	45	35	31	32	
		IN 109-110	1	0	0	0	2	
		IN 109-110	2	36	9	10	10	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	2	2	
THYROID GLAND	(4200)	IN 109-110	1	1	0	0	0	1.000 0.728 0.770
GANGLIONEUROMA, INTERSPERS	(420010)	IN 109-110	2	35	9	10	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
PARATHYROID GLANDS	(4300)	IN 109-110	1	1	0	0	0	1.000 0.728 0.770
ADENOMA	(430001)	IN 109-110	2	35	9	10	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
ADRENAL GLANDS	(4400)	IN 109-110	1	1	0	0	0	1.000 0.825 0.848
MALIGNANT PHEOCHROMOCYTOM	(440015)	IN 109-110	2	35	9	10	12	
	FA 105	1	1	0	0	0		
	FA 105	2	69	34	37	38		
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0	
ADRENAL GLANDS	(4400)	IN 92-108	1	3	2	0	1	0.966 0.957 0.960
CORTICAL ADENOMA	(440019)	IN 92-108	2	42	34	33	31	
		IN 109-110	1	7	0	0	0	
		IN 109-110	2	29	9	10	12	
Spontaneous tumor pct: 9% in ctrl. - Total			-	10	2	0	1	
ADRENAL GLANDS	(4400)	IN 109-110	1	1	0	0	0	1.000 0.728 0.770
BENIGN PHEOCHROMOCYTOMA	(440024)	IN 109-110	2	35	9	10	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
ADRENAL GLANDS	(4400)	IN 92-108	1	0	1	0	0	0.691 0.750 0.788
CORTICAL CARCINOMA	(440027)	IN 92-108	2	45	35	33	32	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0	
ADRENAL GLANDS	(4400)	FA 91	1	1	0	0	0	1.000 0.759 0.797
HISTIOCYTIC SARCOMATOUS I	(440028)	FA 91	2	81	45	43	44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 92-108	1	0	0	1	0	0.330 0.355 0.379
MALIGNANT LYMPHOMA	(450001)	IN 92-108	2	45	36	32	32	
		IN 109-110	1	1	0	0	0	
		IN 109-110	2	35	9	10	12	
	FA 79	1	0	0	0	1		
	FA 79	2	96	50	51	47		
	FA 82	1	0	1	0	0		
	FA 82	2	95	48	51	46		
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	1	1	
HEMOLYMPHORET. SYS.	(4500)	IN 109-110	1	1	0	0	0	1.000 0.822 0.845
MALIGNANT FIBROUS HISTIOC	(450004)	IN 109-110	2	35	9	10	12	
	FA 29	1	1	0	0	0		
	FA 29	2	104	55	53	55		
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 92-108	1	1	0	0	0	0.953 0.884 0.898
HISTIOCYTIC SARCOMA	(450005)	IN 92-108	2	44	36	33	32	
	FA 53	1	0	1	0	0		

	FA 53	2	104	53	52	54	
	FA 91	1	1	0	0	0	
	FA 91	2	81	45	43	44	
Spontaneous tumor pct: 2%	in ctrl. - Total	-	2	1	0	0	
SPLEEN	(4600) FA 107	1	1	0	0	0	1.000 0.754 0.792
HISTIOCYTIC SARCOMA INFIL	(460008) FA 107	2	57	25	26	28	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	0	0	0	
THYMUS	(5000) IN 92-108	1	0	1	0	1	0.255 0.211 0.238
MALIGNANT THYMOMA	(500006) IN 92-108	2	45	35	33	31	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	1	0	1	
THYMUS	(5000) IN 92-108	1	2	2	0	1	0.886 0.878 0.887
BENIGN THYMOMA	(500007) IN 92-108	2	43	34	33	31	
	IN 109-110	1	4	0	0	0	
	IN 109-110	2	32	9	10	12	
Spontaneous tumor pct: 5%	in ctrl. - Total	-	6	2	0	1	
MESENT. LYMPH NODE	(5104) IN 109-110	1	0	1	0	0	0.462 0.701 0.745
HEMANGIOMA	(510406) IN 109-110	2	36	8	10	12	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	0	1	0	0	
ILIAC LYMPH NODE	(5106) IN 79-91	1	1	0	0	0	1.000 0.735 0.782
HISTIOCYTIC SARCOMATOUS I	(510610) IN 79-91	2	14	5	8	4	
Spontaneous tumor pct: <= 1%	in ctrl. - Total	-	1	0	0	0	
MAMMARY GLAND	(5600) IN 53-78	1	0	1	0	0	0.900 0.885 0.892
ADENOCARCINOMA	(560003) IN 53-78	2	8	3	1	6	
	IN 79-91	1	3	0	0	0	
	IN 79-91	2	12	5	7	4	
	IN 92-108	1	1	0	1	1	
	IN 92-108	2	44	36	32	31	
	IN 109-110	1	5	0	0	0	
	IN 109-110	2	31	9	10	12	
	FA 86	1	0	0	1	0	
	FA 86	2	88	46	46	44	
Spontaneous tumor pct: 8%	in ctrl. - Total	-	9	1	2	1	
MAMMARY GLAND	(5600) IN 53-78	1	1	1	0	0	0.379 0.385 0.397
FIBROADENOMA	(560004) IN 53-78	2	7	3	1	6	
	IN 79-91	1	0	0	2	1	
	IN 79-91	2	15	5	6	3	
	IN 92-108	1	3	2	2	2	
	IN 92-108	2	42	33	31	30	
	IN 109-110	1	2	0	1	1	
	IN 109-110	2	34	9	9	11	
	FA 99	1	0	1	0	0	
	FA 99	2	76	41	41	42	
Spontaneous tumor pct: 5%	in ctrl. - Total	-	6	4	5	4	
MAMMARY GLAND	(5600) IN 92-108	1	2	0	0	0	1.000 0.889 0.903
ADENOMA	(560006) IN 92-108	2	43	36	33	32	
	IN 109-110	1	1	0	0	0	
	IN 109-110	2	35	9	10	12	
Spontaneous tumor pct: 3%	in ctrl. - Total	-	3	0	0	0	
SKIN	(5700) IN 92-108	1	0	0	0	1	0.219 0.035 0.046

FIBROSARCOMA	(570008)	IN 92-108	2	45	36	33	31	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
SKIN	(5700)	IN 109-110	1	1	0	0	0	1.000 0.728 0.770
LIPOMA	(570011)	IN 109-110	2	35	9	10	12	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
SKIN	(5700)	FA 82	1	0	0	0	1	0.190 0.025 0.033
SQUAMOUS CELL CARCINOMA	(570012)	FA 82	2	95	49	51	45	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
SKIN	(5700)	IN 92-108	1	0	0	1	0	0.445 0.494 0.544
BENIGN HAIR FOLLICLE TUMO	(570017)	IN 92-108	2	45	36	32	32	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0	
BODY CAVITIES	(6800)	IN 92-108	1	0	0	0	1	0.219 0.035 0.046
MESOTHELIOMA	(680003)	IN 92-108	2	45	36	33	31	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
BODY CAVITIES	(6800)	FA 91	1	1	0	0	0	1.000 0.759 0.797
HISTIOCYTIC SARCOMATOUS I	(680006)	FA 91	2	81	45	43	44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
BODY CAVITIES	(6800)	FA 77	1	1	0	0	0	1.000 0.756 0.795
SCHWANNOMA	(680009)	FA 77	2	97	50	51	49	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
BODY CAVITIES	(6800)	FA 73	1	0	1	0	0	0.208 0.185 0.210
HEMANGIOMA	(680010)	FA 73	2	99	51	51	50	
		FA 99	1	0	0	0	1	
		FA 99	2	76	42	41	41	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	1	

Table 4e

Analysis of Carcinogenic Potential in Female Rat
 Test of Dose-Response (Tumor) Positive Linear Trend
 Study No.

Run Date & Time: September 15, 1999 (7:42)

Source: C:\NG\rat567.dat

Note: Dose Levels Included: CTRL LOW MED HIGH (0 0.003 0.03 0.1)
 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.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
CEREBRUM	(0101)	IN 92-109	1	1 0 0 0	1.000 0.768 1.000
MENINGIOMA	(010105)	IN 92-109	2	69 39 40 42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
CEREBRUM	(0101)	IN 92-109	1	1 0 0 0	1.000 0.768 1.000
GRANULAR CELL TUMOR	(010107)	IN 92-109	2	69 39 40 42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 82	1	1 0 0 0	1.000 0.760 1.000
HEMANGIOSARCOMA	(090015)	FA 82	2	94 46 48 50	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 91	1	1 0 0 0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(090020)	FA 91	2	81 41 43 43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
ORAL CAVITY	(1000)	FA 68	1	0 1 0 0	0.607 0.734 1.000
ODONTOMA	(100001)	FA 68	2	102 50 54 53	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 0 0	
STOMACH	(1500)	FA 91	1	1 0 0 0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(150014)	FA 91	2	81 41 43 43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
DUODENUM	(1601)	IN 110-110	1	1 0 0 0	1.000 0.660 1.000
FIBROMA	(160107)	IN 110-110	2	10 2 2 1	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
JEJUNUM	(1602)	IN 92-109	1	0 1 0 0	0.636 0.745 1.000
ADENOCARCINOMA	(160204)	IN 92-109	2	69 38 40 42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 0 0	
LIVER	(1800)	IN 79-91	1	0 0 0 1	0.005 0.002 0.925
HEPATOCELLULAR ADENOMA	(180004)	IN 79-91	2	15 7 8 6	
		IN 92-109	1	1 0 3 4	
		IN 92-109	2	69 39 37 38	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 3 5	(Exact P<0.025)
LIVER	(1800)	IN 92-109	1	0 0 0 1	0.219 0.035 1.000
HEPATOCELLULAR CARCINOMA	(180021)	IN 92-109	2	70 39 40 41	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 0 1	
PANCREAS	(2000)	IN 79-91	1	0 0 0 1	0.189 0.024 1.000

ACINAR CELL CARCINOMA	(200001)	IN 79-91	2	15	7	8	6	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
PANCREAS	(2000)	IN 92-109	1	1	0	0	0	1.000 0.768 1.000
ISLET CELL ADENOMA	(200003)	IN 92-109	2	69	39	40	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
PANCREAS	(2000)	FA 83	1	0	0	0	1	0.211 0.032 1.000
SCHWANNOMA, MALIGNANT	(200008)	FA 83	2	94	46	47	49	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
KIDNEYS	(2100)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(210018)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
URETERS	(2200)	IN 79-91	1	1	0	0	0	1.000 0.755 1.000
HISTIOCYTIC SARCOMATOUS I	(220003)	IN 79-91	2	14	7	8	7	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
OVIDUCT	(3300)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(330002)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
UTERUS (HORN)	(3400)	IN 79-91	1	1	0	1	1	0.029 0.024 0.578
ADENOCARCINOMA	(340001)	IN 79-91	2	13	5	3	4	
		IN 92-109	1	4	2	8	2	
		IN 92-109	2	63	37	31	36	
		FA 72	1	0	0	1	0	
		FA 72	2	99	49	53	51	
		FA 78	1	0	0	0	1	
		FA 78	2	97	49	50	50	
		FA 80	1	0	1	0	0	
		FA 80	2	96	47	50	50	
		FA 81	1	0	1	1	0	
		FA 81	2	95	46	49	50	
		FA 84	1	0	0	0	2	
		FA 84	2	94	46	47	46	
		FA 87	1	1	0	1	0	
		FA 87	2	84	45	45	44	
		FA 90	1	0	0	1	0	
		FA 90	2	82	41	43	43	
		FA 91	1	0	0	1	0	
		FA 91	2	82	41	42	43	
		FA 92	1	0	0	0	1	
		FA 92	2	81	41	42	42	
		FA 95	1	0	0	1	1	
		FA 95	2	78	40	39	36	
		FA 103	1	0	0	0	1	
		FA 103	2	73	37	36	34	
		FA 106	1	1	0	0	0	
		FA 106	2	68	35	36	32	
		FA 107	1	1	0	0	1	
		FA 107	2	57	25	26	21	
		FA 108	1	1	0	0	0	
		FA 108	2	49	20	20	13	
Spontaneous tumor pct: 8% in ctrl. - Total			-	9	4	15	10	
UTERUS (HORN)	(3400)	FA 69	1	1	0	0	0	1.000 0.760 1.000

FIBROMA	(340002)	FA 69	2	100	50	54	53	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
UTERUS (HORN)	(3400)	IN 92-109	1	0	1	0	0	0.633 0.744 1.000
STROMAL CELL SARCOMA	(340003)	IN 92-109	2	70	38	40	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0	
UTERUS (HORN)	(3400)	IN 53-78	1	0	1	0	0	0.994 0.991 1.000
ENDOMETRIAL STROMAL POLYP	(340005)	IN 53-78	2	8	4	5	3	
		IN 79-91	1	3	1	1	0	
		IN 79-91	2	12	6	7	7	
		IN 92-109	1	13	6	6	2	
		IN 92-109	2	57	33	34	40	
		IN 110-110	1	3	0	1	0	
		IN 110-110	2	8	2	1	1	
Spontaneous tumor pct: 17% in ctrl. - Total			-	19	8	8	2	
UTERUS (HORN)	(3400)	IN 53-78	1	1	0	0	0	1.000 0.742 1.000
SCHWANNOMA	(340012)	IN 53-78	2	7	5	5	3	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
UTERUS (HORN)	(3400)	IN 92-109	1	0	0	0	1	0.219 0.035 1.000
ENDOMETRIAL ADENOMA	(340013)	IN 92-109	2	70	39	40	41	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
UTERUS (HORN)	(3400)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(340017)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
UTERUS (HORN)	(3400)	FA 96	1	0	0	1	0	0.390 0.451 1.000
LEIOMYOSARCOMA	(340021)	FA 96	2	78	39	38	36	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0	
UTERUS (HORN)	(3400)	IN 92-109	1	0	0	1	0	0.429 0.488 1.000
SQUAMOUS CELL CARCINOMA	(340022)	IN 92-109	2	70	39	39	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0	
CERVIX	(3401)	IN 79-91	1	1	0	0	0	1.000 0.905 1.000
STROMAL POLYP	(340108)	IN 79-91	2	14	7	8	7	
		IN 92-109	1	2	0	0	0	
		IN 92-109	2	68	39	40	42	
		IN 110-110	1	1	0	0	0	
		IN 110-110	2	10	2	2	1	
Spontaneous tumor pct: 4% in ctrl. - Total			-	4	0	0	0	
CERVIX	(3401)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(340111)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
CERVIX	(3401)	IN 92-109	1	0	1	0	0	0.633 0.744 1.000
FIBROSARCOMA	(340113)	IN 92-109	2	70	38	40	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0	
CERVIX	(3401)	FA 85	1	0	0	0	1	0.206 0.184 1.000
SARCOMA	(340116)	FA 85	2	90	45	47	45	
		FA 88	1	0	1	0	0	
		FA 88	2	83	44	45	44	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	1	

VAGINA	(3500)	IN 79-91	1	0	0	0	1	0.189	0.024	1.000
POLYP	(350006)	IN 79-91	2	15	7	8	6			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
VAGINA	(3500)	IN 92-109	1	0	0	0	2	0.047	0.005	1.000
SQUAMOUS CELL CARCINOMA	(350010)	IN 92-109	2	70	39	40	40			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	2			
VAGINA	(3500)	IN 92-109	1	0	0	0	1	0.219	0.035	1.000
BENIGN GRANULAR CELL TUMO	(350011)	IN 92-109	2	70	39	40	41			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
CLITORAL GLANDS	(3700)	IN 92-109	1	0	1	0	0	0.633	0.744	1.000
SQUAMOUS CELL CARCINOMA	(370002)	IN 92-109	2	70	38	40	42			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0			
PITUITARY GLAND	(4100)	IN 53-78	1	1	0	1	1	0.561	0.565	0.927
ADENOMA OF PARS DISTALIS,	(410001)	IN 53-78	2	3	1	1	1			
		IN 79-91	1	1	1	0	1			
		IN 79-91	2	3	4	5	4			
		IN 92-109	1	41	19	16	21			
		IN 92-109	2	21	16	19	13			
		IN 110-110	1	10	1	1	0			
		IN 110-110	2	1	1	1	1			
	FA 54	1	0	1	0	0				
	FA 54	2	104	52	55	53				
	FA 66	1	0	1	0	0				
	FA 66	2	103	51	54	53				
	FA 67	1	1	0	0	0				
	FA 67	2	102	51	54	53				
	FA 69	1	1	0	0	1				
	FA 69	2	100	50	54	52				
	FA 70	1	0	1	0	0				
	FA 70	2	99	49	54	51				
	FA 72	1	0	0	1	0				
	FA 72	2	99	49	53	51				
	FA 73	1	0	0	1	0				
	FA 73	2	99	49	51	51				
	FA 76	1	1	0	0	0				
	FA 76	2	98	49	51	51				
	FA 77	1	0	0	1	0				
	FA 77	2	98	49	50	51				
	FA 78	1	1	1	0	0				
	FA 78	2	96	48	50	51				
	FA 80	1	1	0	0	0				
	FA 80	2	95	48	50	50				
	FA 81	1	0	0	1	0				
	FA 81	2	95	47	49	50				
	FA 84	1	3	1	0	0				
	FA 84	2	91	45	47	48				
	FA 85	1	2	0	1	1				
	FA 85	2	88	45	46	45				
	FA 86	1	3	0	0	0				
	FA 86	2	85	45	46	44				
	FA 87	1	1	0	0	0				
	FA 87	2	84	45	46	44				
	FA 88	1	0	1	1	0				

FA 88	2	83 44 44 44	
FA 89	1	1 0 0 1	
FA 89	2	82 41 44 43	
FA 92	1	2 0 0 1	
FA 92	2	79 41 42 42	
FA 93	1	0 1 1 2	
FA 93	2	79 40 41 38	
FA 94	1	1 0 1 0	
FA 94	2	78 40 40 38	
FA 95	1	0 1 0 0	
FA 95	2	78 39 40 37	
FA 96	1	0 0 0 1	
FA 96	2	78 39 39 35	
FA 98	1	1 0 1 0	
FA 98	2	77 39 37 35	
FA 100	1	1 0 0 0	
FA 100	2	75 38 37 35	
FA 101	1	1 0 1 0	
FA 101	2	73 38 36 35	
FA 102	1	0 1 0 0	
FA 102	2	73 37 36 35	
FA 103	1	0 0 0 1	
FA 103	2	73 37 36 34	
FA 104	1	1 0 0 1	
FA 104	2	72 37 36 32	
FA 105	1	0 1 0 0	
FA 105	2	70 35 36 32	
FA 107	1	1 0 0 2	
FA 107	2	57 25 26 20	
FA 108	1	0 0 1 0	
FA 108	2	50 20 19 13	
Spontaneous tumor pct: 69% in ctrl. - Total	-	76 31 29 34	
PITUITARY GLAND (4100) IN 92-109	1	1 0 0 0	1.000 0.768 1.000
CARCINOMA OF PARS DISTALI (410009) IN 92-109	2	69 39 40 42	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1 0 0 0	
THYROID GLAND (4200) IN 92-109	1	9 2 1 0	0.999 0.993 1.000
C-CELL ADENOMA (420001) IN 92-109	2	61 37 39 42	
	IN 110-110	1 3 0 0 0	
	IN 110-110	2 8 2 2 1	
Spontaneous tumor pct: 11% in ctrl. - Total	-	12 2 1 0	
THYROID GLAND (4200) IN 92-109	1	0 0 0 2	0.047 0.005 1.000
C-CELL CARCINOMA (420006) IN 92-109	2	70 39 40 40	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0 0 0 2	
THYROID GLAND (4200) IN 79-91	1	1 0 0 0	0.851 0.829 1.000
FOLLICULAR CELL ADENOMA (420008) IN 79-91	2	14 7 8 7	
	IN 92-109	1 0 1 0 0	
	IN 92-109	2 70 38 40 42	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1 1 0 0	
THYROID GLAND (4200) IN 110-110	1	1 0 0 0	1.000 0.660 1.000
GANGLIONEUROMA, INTERSPERS (420010) IN 110-110	2	10 2 2 1	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1 0 0 0	
PARATHYROID GLANDS (4300) IN 92-109	1	1 1 1 0	0.731 0.785 1.000

ADENOMA	(430001)	IN 92-109	2	69	38	39	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	1	0	
ADRENAL GLANDS	(4400)	IN 92-109	1	1	0	0	0	1.000 0.841 1.000
MALIGNANT PHEOCHROMOCYTOM	(440015)	IN 92-109	2	68	39	40	42	
	FA 105		1	1	0	0	0	
	FA 105		2	69	36	36	32	
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0	
ADRENAL GLANDS	(4400)	IN 92-109	1	9	3	2	0	0.998 0.991 1.000
CORTICAL ADENOMA	(440019)	IN 92-109	2	61	36	38	42	
		IN 110-110	1	1	0	0	0	
		IN 110-110	2	10	2	2	1	
Spontaneous tumor pct: 9% in ctrl. - Total			-	10	3	2	0	
ADRENAL GLANDS	(4400)	IN 79-91	1	0	1	0	0	0.715 0.775 1.000
BENIGN PHEOCHROMOCYTOMA	(440024)	IN 79-91	2	15	6	8	7	
		IN 92-109	1	1	0	1	0	
		IN 92-109	2	69	39	39	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	1	0	
ADRENAL GLANDS	(4400)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(440028)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 79-91	1	0	0	0	1	0.102 0.088 1.000
MALIGNANT LYMPHOMA	(450001)	IN 79-91	2	15	7	8	6	
		IN 92-109	1	0	1	1	1	
		IN 92-109	2	70	38	39	41	
		IN 110-110	1	1	0	0	0	
		IN 110-110	2	10	2	2	1	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	1	1	2	
HEMOLYMPHORET. SYS.	(4500)	IN 92-109	1	0	0	0	1	0.219 0.035 1.000
MYELOID LEUKEMIA	(450002)	IN 92-109	2	70	39	40	41	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1	
HEMOLYMPHORET. SYS.	(4500)	IN 110-110	1	1	0	0	0	1.000 0.792 1.000
MALIGNANT FIBROUS HISTIOC	(450004)	IN 110-110	2	10	2	2	1	
	FA 29		1	1	0	0	0	
	FA 29		2	104	54	55	55	
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 92-109	1	1	0	0	0	1.000 0.845 1.000
HISTIOCYTIC SARCOMA	(450005)	IN 92-109	2	69	39	40	42	
	FA 91		1	1	0	0	0	
	FA 91		2	81	41	43	43	
Spontaneous tumor pct: 2% in ctrl. - Total			-	2	0	0	0	
SPLEEN	(4600)	FA 107	1	1	0	0	0	1.000 0.739 1.000
HISTIOCYTIC SARCOMA INFIL	(460008)	FA 107	2	57	25	26	22	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
THYMUS	(5000)	IN 92-109	1	5	3	0	2	0.748 0.766 1.000
BENIGN THYMOMA	(500007)	IN 92-109	2	65	36	40	40	
		IN 110-110	1	1	0	0	0	
		IN 110-110	2	10	2	2	1	
Spontaneous tumor pct: 5% in ctrl. - Total			-	6	3	0	2	

ILIAC LYMPH NODE	(5106)	IN 79-91	1	1	0	0	0	1.000	0.755	1.000
HISTIOCYTIC SARCOMATOUS I	(510610)	IN 79-91	2	14	7	8	7			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
MAMMARY GLAND	(5600)	IN 53-78	1	0	1	0	0	0.006	0.004	0.597
ADENOCARCINOMA	(560003)	IN 53-78	2	8	4	5	3			
		IN 79-91	1	3	0	0	1			
		IN 79-91	2	12	7	8	6			
		IN 92-109	1	4	1	2	9			
		IN 92-109	2	66	38	38	33			
		IN 110-110	1	2	0	0	0			
		IN 110-110	2	9	2	2	1			
Spontaneous tumor pct: 8% in ctrl. - Total			-	9	2	2	10			
MAMMARY GLAND	(5600)	IN 53-78	1	1	0	0	0	0.836	0.820	1.000
FIBROADENOMA	(560004)	IN 53-78	2	7	5	5	3			
		IN 92-109	1	4	1	1	1			
		IN 92-109	2	66	38	39	41			
		IN 110-110	1	1	0	0	0			
		IN 110-110	2	10	2	2	1			
Spontaneous tumor pct: 5% in ctrl. - Total			-	6	1	1	1			
MAMMARY GLAND	(5600)	IN 92-109	1	3	1	0	1	0.701	0.682	1.000
ADENOMA	(560006)	IN 92-109	2	67	38	40	41			
Spontaneous tumor pct: 3% in ctrl. - Total			-	3	1	0	1			
MAMMARY GLAND	(5600)	FA 82	1	0	0	1	0	0.410	0.474	1.000
CARCINOSARCOMA	(560011)	FA 82	2	95	46	47	50			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
SKIN	(5700)	IN 92-109	1	0	0	0	1	0.219	0.035	1.000
FIBROSARCOMA	(570008)	IN 92-109	2	70	39	40	41			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
SKIN	(5700)	IN 92-109	1	1	0	0	0	0.662	0.680	1.000
LIPOMA	(570011)	IN 92-109	2	69	39	40	42			
		FA 58	1	0	0	1	0			
		FA 58	2	104	52	54	53			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	1	0			
SKIN	(5700)	IN 92-109	1	0	0	0	1	0.219	0.035	1.000
BASAL CELL CARCINOMA	(570013)	IN 92-109	2	70	39	40	41			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
SKIN	(5700)	IN 92-109	1	0	0	1	0	0.429	0.488	1.000
FIBROMA	(570018)	IN 92-109	2	70	39	39	42			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
SKIN	(5700)	IN 92-109	1	0	0	1	0	0.429	0.488	1.000
SEBACEOUS GLAND CARCINOMA	(570020)	IN 92-109	2	70	39	39	42			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0			
BONE	(5900)	FA 92	1	0	0	0	1	0.207	0.030	1.000
OSTEOSARCOMA	(590004)	FA 92	2	81	41	42	42			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	0	1			
BODY CAVITIES	(6800)	IN 92-109	1	0	1	0	0	0.633	0.744	1.000

LIPOMA, ABDOMINAL CAVITY	(680002)	IN 92-109	2	70	38	40	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0	
BODY CAVITIES	(6800)	IN 92-109	1	0	0	1	0	0.429 0.488 1.000
MESOTHELIOMA	(680003)	IN 92-109	2	70	39	39	42	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	0	1	0	
BODY CAVITIES	(6800)	FA 91	1	1	0	0	0	1.000 0.760 1.000
HISTIOCYTIC SARCOMATOUS I	(680006)	FA 91	2	81	41	43	43	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	
BODY CAVITIES	(6800)	FA 77	1	1	0	0	0	1.000 0.759 1.000
SCHWANNOMA	(680009)	FA 77	2	97	49	51	51	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0	

Table 4f

Analysis of Carcinogenic Potential in Female Rat
 Test of Dose-Response (Tumor) Positive Linear Trend
 Study No. _____

Run Date & Time: September 15, 1999 (7:12)

Source: C:\NG\rat789.dat

Note: Dose Levels Included: CTRL LOW MED HIGH (0 0.3 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 TIME TYPES STRATA	ROW NO.	2xC CONTINGENCY -----TABLES-----	EXACT ASYMP ASYMP PROB PROB PROB /CONT CORR =P(STAT .GE. OBSERVED)
CEREBRUM	(0101)	IN 92-109	1	1 0 0 0	1.000 0.752 0.792
MENINGIOMA	(010105)	IN 92-109	2	69 40 39 33	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
CEREBRUM	(0101)	IN 92-109	1	1 0 0 0	1.000 0.752 0.792
GRANULAR CELL TUMOR	(010107)	IN 92-109	2	69 40 39 33	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 82	1	1 0 0 0	1.000 0.740 0.783
HEMANGIOSARCOMA	(090015)	FA 82	2	94 48 45 38	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
LUNGS	(0900)	FA 91	1	1 0 0 0	1.000 0.743 0.785
HISTIOCYTIC SARCOMATOUS I	(090020)	FA 91	2	81 44 41 34	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
TONGUE	(1100)	IN 92-109	1	0 1 0 0	0.615 0.725 0.768
SQUAMOUS CELL PAPILLOMA	(110005)	IN 92-109	2	70 39 39 33	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 0 0	
STOMACH	(1500)	FA 91	1	1 0 0 0	1.000 0.743 0.785
HISTIOCYTIC SARCOMATOUS I	(150014)	FA 91	2	81 44 41 34	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
DUODENUM	(1601)	IN 110-110	1	1 0 0 0	1.000 0.656 0.729
FIBROMA	(160107)	IN 110-110	2	10 4 2 1	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 0	
ILEUM	(1603)	FA 83	1	0 0 0 1	0.166 0.016 0.023
LEIOMYOSARCOMA	(160303)	FA 83	2	94 46 45 36	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 0 0 1	
LIVER	(1800)	IN 79-91	1	0 0 0 1	0.317 0.155 0.179
HEPATOCELLULAR ADENOMA	(180004)	IN 79-91	2	15 5 5 4	
		IN 92-109	1	1 0 0 0	
		IN 92-109	2	69 40 39 33	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1 0 0 1	
LIVER	(1800)	FA 87	1	0 1 0 0	0.591 0.717 0.761
HEPATOCELLULAR CARCINOMA	(180021)	FA 87	2	85 44 42 36	
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0 1 0 0	

PANCREAS	(2000)	IN 92-109	1	1	0	1	2	0.079	0.039	0.045
ISLET CELL ADENOMA	(200003)	IN 92-109	2	69	40	38	31			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	1	2			
KIDNEYS	(2100)	FA 91	1	1	0	0	0	1.000	0.743	0.785
HISTIOCYTIC SARCOMATOUS I	(210018)	FA 91	2	81	44	41	34			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
URETERS	(2200)	IN 79-91	1	1	0	0	0	1.000	0.728	0.772
HISTIOCYTIC SARCOMATOUS I	(220003)	IN 79-91	2	14	5	5	5			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
OVARIES	(3200)	IN 92-109	1	0	1	0	0	0.615	0.725	0.768
BENIGN GRANULOSA/THECA CE	(320013)	IN 92-109	2	70	39	39	33			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0			
OVIDUCT	(3300)	FA 91	1	1	0	0	0	1.000	0.743	0.785
HISTIOCYTIC SARCOMATOUS I	(330002)	FA 91	2	81	44	41	34			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
UTERUS (HORN)	(3400)	IN 79-91	1	1	0	0	0	0.987	0.957	0.961
ADENOCARCINOMA	(340001)	IN 79-91	2	13	5	5	5			
		IN 92-109	1	4	0	0	0			
		IN 92-109	2	63	40	39	33			
		IN 110-110	1	0	1	1	0			
		IN 110-110	2	11	3	1	1			
		FA 87	1	1	0	0	0			
		FA 87	2	84	45	42	36			
		FA 106	1	1	0	0	0			
		FA 106	2	68	42	33	27			
		FA 107	1	1	0	0	0			
		FA 107	2	57	31	23	16			
		FA 108	1	1	0	0	0			
		FA 108	2	49	24	15	10			
Spontaneous tumor pct: 8% in ctrl. - Total			-	9	1	1	0			
UTERUS (HORN)	(3400)	FA 69	1	1	0	0	0	1.000	0.746	0.787
FIBROMA	(340002)	FA 69	2	100	51	49	44			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
UTERUS (HORN)	(3400)	FA 79	1	0	1	0	0	0.582	0.714	0.759
STROMAL CELL SARCOMA	(340003)	FA 79	2	96	48	46	39			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	0	1	0	0			
UTERUS (HORN)	(3400)	IN 79-91	1	3	0	0	0	0.998	0.995	0.995
ENDOMETRIAL STROMAL POLYP	(340005)	IN 79-91	2	12	5	5	5			
		IN 92-109	1	13	6	1	1			
		IN 92-109	2	57	34	38	32			
		IN 110-110	1	3	1	1	0			
		IN 110-110	2	8	3	1	1			
Spontaneous tumor pct: 17% in ctrl. - Total			-	19	7	2	1			
UTERUS (HORN)	(3400)	IN 53-78	1	1	0	0	0	1.000	0.816	0.845
SCHWANNOMA	(340012)	IN 53-78	2	7	5	6	9			
Spontaneous tumor pct: <= 1% in ctrl. - Total			-	1	0	0	0			
UTERUS (HORN)	(3400)	FA 91	1	1	0	0	0	1.000	0.743	0.785
HISTIOCYTIC SARCOMATOUS I	(340017)	FA 91	2	81	44	41	34			

Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1	0	0	0	
CERVIX (3401) IN 79-91	1	0	1	0	0	0.500 0.700 0.746
SQUAMOUS CELL CARCINOMA (340101) IN 79-91	2	15	4	5	5	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	1	0	0	
CERVIX (3401) IN 79-91	1	1	0	0	0	0.642 0.635 0.657
STROMAL POLYP (340108) IN 79-91	2	14	5	5	5	
IN 92-109	1	2	1	0	1	
IN 92-109	2	68	39	39	32	
IN 110-110	1	1	0	0	0	
IN 110-110	2	10	4	2	1	
Spontaneous tumor pct: 4% in ctrl. - Total	-	4	1	0	1	
CERVIX (3401) FA 91	1	1	0	0	0	1.000 0.743 0.785
HISTIOCYTIC SARCOMATOUS I (340111) FA 91	2	81	44	41	34	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1	0	0	0	
CERVIX (3401) IN 92-109	1	0	0	0	1	0.181 0.021 0.029
BENIGN GRANULAR CELL TUMO (340112) IN 92-109	2	70	40	39	32	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	0	0	1	
CERVIX (3401) IN 92-109	1	0	0	0	1	0.181 0.021 0.029
FIBROSARCOMA (340113) IN 92-109	2	70	40	39	32	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	0	0	1	
PITUITARY GLAND (4100) IN 53-78	1	1	1	1	0	0.553 0.556 0.562
ADENOMA OF PARS DISTALIS, (410001) IN 53-78	2	3	1	2	4	
IN 79-91	1	1	2	0	1	
IN 79-91	2	3	1	1	3	
IN 92-109	1	41	22	21	15	
IN 92-109	2	21	16	11	13	
IN 110-110	1	10	1	2	0	
IN 110-110	2	1	3	0	1	
FA 28	1	0	0	0	1	
FA 28	2	105	55	53	52	
FA 58	1	0	0	1	0	
FA 58	2	104	54	50	48	
FA 59	1	0	1	0	0	
FA 59	2	103	53	50	48	
FA 62	1	0	0	0	1	
FA 62	2	103	53	50	46	
FA 64	1	0	1	0	0	
FA 64	2	103	52	50	46	
FA 65	1	0	0	0	2	
FA 65	2	103	52	50	44	
FA 67	1	1	0	0	0	
FA 67	2	102	52	50	44	
FA 69	1	1	0	0	0	
FA 69	2	100	51	49	44	
FA 70	1	0	1	0	0	
FA 70	2	99	50	49	44	
FA 71	1	0	0	1	0	
FA 71	2	99	50	48	44	
FA 72	1	0	0	0	1	
FA 72	2	99	50	48	43	
FA 76	1	1	0	1	1	
FA 76	2	98	50	47	39	

FA 78	1	1	0	0	0					
FA 78	2	96	49	46	39					
FA 80	1	1	0	1	0					
FA 80	2	95	48	45	39					
FA 82	1	0	1	0	0					
FA 82	2	95	47	45	38					
FA 84	1	3	1	1	0					
FA 84	2	91	45	43	36					
FA 85	1	2	0	0	0					
FA 85	2	88	45	43	36					
FA 86	1	3	0	1	0					
FA 86	2	85	45	42	36					
FA 87	1	1	0	1	0					
FA 87	2	84	45	41	36					
FA 88	1	0	0	0	1					
FA 88	2	83	44	41	35					
FA 89	1	1	0	0	0					
FA 89	2	82	44	41	35					
FA 92	1	2	0	0	0					
FA 92	2	79	44	41	34					
FA 93	1	0	0	2	0					
FA 93	2	79	44	39	34					
FA 94	1	1	0	0	1					
FA 94	2	78	44	39	32					
FA 96	1	0	0	1	0					
FA 96	2	78	44	36	32					
FA 97	1	0	0	1	0					
FA 97	2	78	44	35	32					
FA 98	1	1	0	1	1					
FA 98	2	77	44	34	31					
FA 100	1	1	0	0	0					
FA 100	2	75	44	34	30					
FA 101	1	1	0	0	1					
FA 101	2	73	44	34	29					
FA 102	1	0	1	0	0					
FA 102	2	73	43	34	29					
FA 104	1	1	0	0	0					
FA 104	2	72	42	33	28					
FA 105	1	0	0	0	1					
FA 105	2	70	42	33	27					
FA 106	1	0	0	0	1					
FA 106	2	69	42	33	26					
FA 107	1	1	1	2	0					
FA 107	2	57	30	21	16					
Spontaneous tumor pct: 69% in ctrl. - Total		-	76	33	38	28				
PITUITARY GLAND	(4100)	IN 92-109	1	1	0	0	0	1.000	0.752	0.792
CARCINOMA OF PARS DISTALI	(410009)	IN 92-109	2	69	40	39	33			
Spontaneous tumor pct: <= 1% in ctrl. - Total		-		1	0	0	0			
THYROID GLAND	(4200)	IN 92-109	1	9	2	1	5	0.284	0.301	0.312
C-CELL ADENOMA	(420001)	IN 92-109	2	61	38	38	28			
		IN 110-110	1	3	0	0	0			
		IN 110-110	2	8	4	2	1			
Spontaneous tumor pct: 11% in ctrl. - Total		-		12	2	1	5			
THYROID GLAND	(4200)	IN 79-91	1	1	0	0	0	0.110	0.090	0.100
FOLLICULAR CELL ADENOMA	(420008)	IN 79-91	2	14	5	5	5			

		IN 92-109	1	0	1	1	2	
		IN 92-109	2	70	39	38	31	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	1	1	2	
THYROID GLAND	(4200)	IN 110-110	1	1	0	0	0	1.000 0.656 0.729
GANGLIONEUROMA, INTERSPERS	(420010)	IN 110-110	2	10	4	2	1	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0	
PARATHYROID GLANDS	(4300)	IN 92-109	1	1	1	0	1	0.372 0.334 0.363
ADENOMA	(430001)	IN 92-109	2	69	39	39	32	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	1	0	1	
ADRENAL GLANDS	(4400)	IN 92-109	1	1	0	0	1	0.142 0.080 0.090
MALIGNANT PHEOCHROMOCYTOM	(440015)	IN 92-109	2	68	40	39	32	
	FA 73	1	0	0	0	1		
	FA 73	2	99	50	48	40		
	FA 105	1	1	0	0	0		
	FA 105	2	69	42	33	28		
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	0	0	2	
ADRENAL GLANDS	(4400)	IN 92-109	1	9	1	0	1	0.940 0.934 0.939
CORTICAL ADENOMA	(440019)	IN 92-109	2	61	39	39	32	
		IN 110-110	1	1	0	0	0	
		IN 110-110	2	10	4	2	1	
Spontaneous tumor pct: 9% in ctrl.	-	Total	-	10	1	0	1	
ADRENAL GLANDS	(4400)	IN 92-109	1	1	0	0	2	0.085 0.025 0.030
BENIGN PHEOCHROMOCYTOMA	(440024)	IN 92-109	2	69	40	39	31	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	2	
ADRENAL GLANDS	(4400)	FA 91	1	1	0	0	0	1.000 0.743 0.785
HISTIOCYTIC SARCOMATOUS I	(440028)	FA 91	2	81	44	41	34	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 110-110	1	1	0	0	0	0.215 0.060 0.076
MALIGNANT LYMPHOMA	(450001)	IN 110-110	2	10	4	2	1	
	FA 98	1	0	0	0	1		
	FA 98	2	78	44	35	31		
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	1	
HEMOLYMPHORET. SYS.	(4500)	IN 110-110	1	1	0	0	0	1.000 0.787 0.817
MALIGNANT FIBROUS HISTIOC	(450004)	IN 110-110	2	10	4	2	1	
	FA 29	1	1	0	0	0		
	FA 29	2	104	55	53	52		
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	0	0	0	
HEMOLYMPHORET. SYS.	(4500)	IN 92-109	1	1	0	0	0	1.000 0.827 0.850
HISTIOCYTIC SARCOMA	(450005)	IN 92-109	2	69	40	39	33	
	FA 91	1	1	0	0	0		
	FA 91	2	81	44	41	34		
Spontaneous tumor pct: 2% in ctrl.	-	Total	-	2	0	0	0	
SPLEEN	(4600)	FA 107	1	1	0	0	0	1.000 0.715 0.765
HISTIOCYTIC SARCOMA INFIL	(460008)	FA 107	2	57	31	23	16	
Spontaneous tumor pct: <= 1% in ctrl.	-	Total	-	1	0	0	0	
THYMUS	(5000)	IN 92-109	1	0	0	1	1	0.110 0.063 0.076
MALIGNANT THYMOMA	(500006)	IN 92-109	2	70	40	38	32	

Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	0	1	1	
THYMUS (5000) IN 92-109	1	5	1	0	0	0.998 0.955 0.960
BENIGN THYMOMA (500007) IN 92-109	2	65	39	39	33	
	IN 110-110	1	1	0	0	
	IN 110-110	2	10	4	2	1
Spontaneous tumor pct: 5% in ctrl. - Total	-	6	1	0	0	
ILIAC LYMPH NODE (5106) IN 79-91	1	1	0	0	0	1.000 0.728 0.772
HISTIOCYTIC SARCOMATOUS I (510610) IN 79-91	2	14	5	5	5	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1	0	0	0	
MANDIB. LYMPH NODES (5108) IN 92-109	1	0	1	0	0	0.615 0.725 0.768
HEMANGIOMA (510809) IN 92-109	2	70	39	39	33	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	1	0	0	
MAMMARY GLAND (5600) IN 79-91	1	3	0	0	0	0.961 0.941 0.946
ADENOCARCINOMA (560003) IN 79-91	2	12	5	5	5	
	IN 92-109	1	4	0	2	0
	IN 92-109	2	66	40	37	33
	IN 110-110	1	2	0	0	0
	IN 110-110	2	9	4	2	1
Spontaneous tumor pct: 8% in ctrl. - Total	-	9	0	2	0	
MAMMARY GLAND (5600) IN 53-78	1	1	0	0	0	0.277 0.279 0.290
FIBROADENOMA (560004) IN 53-78	2	7	4	4	8	
	IN 92-109	1	4	3	2	3
	IN 92-109	2	66	37	36	30
	IN 110-110	1	1	0	0	0
	IN 110-110	2	10	4	2	1
	FA 61	1	0	0	0	1
	FA 61	2	103	53	50	47
	FA 67	1	0	0	1	0
	FA 67	2	103	52	49	44
	FA 76	1	0	1	1	0
	FA 76	2	99	49	47	40
	FA 102	1	0	0	1	0
	FA 102	2	73	44	33	29
Spontaneous tumor pct: 5% in ctrl. - Total	-	6	4	5	4	
MAMMARY GLAND (5600) IN 92-109	1	3	1	0	1	0.623 0.611 0.634
ADENOMA (560006) IN 92-109	2	67	39	39	32	
Spontaneous tumor pct: 3% in ctrl. - Total	-	3	1	0	1	
SKIN (5700) IN 92-109	1	1	0	0	0	1.000 0.752 0.792
LIPOMA (570011) IN 92-109	2	69	40	39	33	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	1	0	0	0	
SKIN (5700) IN 92-109	1	0	0	1	0	0.395 0.448 0.502
SQUAMOUS CELL CARCINOMA (570012) IN 92-109	2	70	40	38	33	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	0	1	0	
SKIN (5700) IN 92-109	1	0	0	0	1	0.181 0.021 0.029
SQUAMOUS CELL PAPILLOMA (570014) IN 92-109	2	70	40	39	32	
Spontaneous tumor pct: <= 1% in ctrl. - Total	-	0	0	0	1	
SKIN (5700) IN 92-109	1	0	1	0	0	0.657 0.790 0.817
SARCOMA, SUBCUTIS (570021) IN 92-109	2	70	38	39	33	

	FA 103	1	0	1	0	0	
	FA 103	2	73	42	33	28	
Spontaneous tumor pct: <= 1% in ctrl. - Total		-	0	2	0	0	
BODY CAVITIES	(6800) FA 91	1	1	0	0	0	1.000 0.743 0.785
HISTIOCYTIC SARCOMATOUS I	(680006) FA 91	2	81	44	41	34	
Spontaneous tumor pct: <= 1% in ctrl. - Total		-	1	0	0	0	
BODY CAVITIES	(6800) FA 72	1	0	0	0	1	0.320 0.159 0.184
SCHWANNOMA	(680009) FA 72	2	99	50	48	43	
	FA 77	1	1	0	0	0	
	FA 77	2	97	49	46	39	
Spontaneous tumor pct: <= 1% in ctrl. - Total		-	1	0	0	1	

NDA 21-098

Yasmin® 28 Tablets (drospirenone/ethinyl estradiol)

Berlex Laboratories, Inc.

The executive CAC/ECAC report was provided during the first review cycle.

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4118101

**APPEARS THIS WAY
ON ORIGINAL**

Executive CAC
January 4, 2000

Committee: Joseph DeGeorge, Ph.D., HFD-024, Chair
Joseph Contrera, Ph.D., HFD-901, Member
Jim Farrelly, Ph.D., HFD-530, Alternate Member
Alex Jordan, Ph.D., Team Leader
Krishan L. Raheja, D.V.M., Ph.D., Presenting Reviewer

Author of Draft: Krishan L. Raheja

The following information reflects a brief summary of the Committee discussion and its recommendations. Detailed study information can be found in the individual review.

NDA #: 21-098

Drug name: Yasmin (drospirenone + ethinyl estradiol)

Sponsor: Berlex Laboratories Inc.

Mouse Carcinogenicity study: The following treatment groups were used in the mouse carcinogenicity study:

Group	Treatment	Dose level (mg/kg/day)		Number of animals	
		EE	DRSP	Main study	Satellite study
1	Control	0	0	110	8
2	EE + DRSP	0.01	1.0	55	39
3	EE + DRSP	0.03	3.0	55	39
4	EE + DRSP	0.1	10.0	55	39
5	EE	0.01	0	55	23
6	EE	0.03	0	55	23
7	EE	0.1	0	55	23
8	DRSP	0	1.0	55	17
9	DRSP	0	3.0	55	17
10	DRSP	0	10.0	55	17

Treatment resulted in a significant decrease in survival in the mid and high dose combination and in the high dose EE alone groups.

Tumor findings consisted of a statistically significant dose-response of pituitary adenomas with combination of DRSP and EE. There were statistically significant dose relationship in carcinomas and carcinosarcomas of the mammary gland and with pituitary adenomas among doses of EE alone. The only significant finding with DRSP alone treatment was a statistically positive dose relationship of carcinomas of the harderian gland.

Rat carcinogenicity study: As in the mouse carcinogenicity, a control and 9 treatment groups were used. The EE/DRSP dose for the low, mid and high dose combination groups 2, 3 and 4 were 0.003/0.3, 0.03/3.0 and 0.1/10.0 mg/kg/day. Groups 5, 6 and 7 had low, mid and high dose of EE alone. Groups 8, 9 and 10 had low, mid and high dose of DRSP alone.

Sponsor was informed that study dose selection would be acceptable if systemic exposure with the high dose was at least 10 times greater than the systemic exposure in humans taking a therapeutic dose.

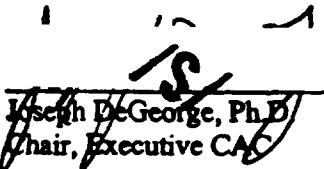
Although PK determination conducted on samples collected at the end of 105 week carcinogenicity study showed that AUC_{0-24h} for DRSP was greater than 10 times the AUC for humans with therapeutic dose, it was extrapolated from AUC_{0-4h} data. Moreover, aliquots of plasma samples from 5 animals were combined to have a single sample for drug determination.

Significant tumor findings were an increase in the incidence of hepatocellular adenomas in the high dose combination group and a significant positive dose-response relationship in the incidence of hepatocellular adenomas among the doses of EE alone. The incidence of uterine adenocarcinoma was increased in the mid and high dose EE alone groups and the incidence of mammary gland adenocarcinoma was increased in the high dose EE alone group. In the high dose DRSP alone group, the incidence of adrenal gland benign pheochromocytoma as well as benign + malignant pheochromocytoma was increased.

Executive committee recommendations and conclusions: The Committee felt that the mouse carcinogenicity study was acceptable, based on increased mortality in the mid and high dose combination and high dose EE alone groups and that the tumors observed should be reported.

The rat study was considered acceptable if the AUC data (which demonstrate a 10 fold higher exposure in the HD animals compared to humans) are valid. There are questions as to how much of the AUC was measured versus how much was calculated from the extrapolation time period. The information provided suggests that a large fraction (over half) of the AUC was contributed by extrapolation, which would not support the value used for the AUC_{0-24h} .

The sponsor should provide evidence that the extrapolation from AUC_{0-4h} to AUC_{0-24h} is valid. The discussion of the tumor findings and reliance on this study are dependent of resolution of this issue.


Joseph DeGeorge, Ph.D.
Chair, Executive CAC

Cc:\

Division file, HFD-580
Team Leader, HFD-580
Reviewer, HFD-580
CSO/PM, HFD-580
ASeifried, HFD-024