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November 5, 1998

Annie Jarabek
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Durham (RTP), NC 27709

Telephone: (919) 541-4114 or 4847

RE: Study 1613-002 - A Neurobehavioral Developmental Study of Ammonium Perchlorate Administered Orally in Drinking Water to Rats
Sponsor's Study Number: 7757A210-1096-25F

Dear Ms. Jarabek:

Enclosed is a copy of the revised Day 12 F1 generation morphometry data tables and statistical output for the above-referenced study.

Morphometrics were requested on the next lower dosage (3 mg/kg/day) because of the potential biological significance of a 20-30% change in the size of some brain regions in the 10 mg/kg/day dosage group, coupled with the statistically significant increase in the corpus callosum size of the Day 12 female pups.

A statistically significant increase in the anterior/posterior cerebellum size and a statistically significant decrease in the caudate putamen size for the Day 12 female pups and a statistical significant decrease in the hippocampal gyrus size for the Day 12 male pups were noted for the reevaluation. Dr. Garman did not believe that these significant findings were treatment-related because they were not dosage-dependent.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Raymond G. York, Ph.D., DABT
Associate Director of Research
and Study Director

RGY:gyb
Enc.

PROTOCOL 1613-002: A NEUROBEHAVIORAL DEVELOPMENTAL STUDY OF AMMONIUM PERCHLORATE ADMINISTERED ORALLY IN DRINKING WATER TO RATS
(SPONSOR'S STUDY NUMBER: 7757A210-1096-25F)

MORPHOMETRIC DATA - DAY 12 - F1 GENERATION MALE RATS - SUBSET 1

Rat Number	Brain Weight	Ant/Post cerebrum	Ant/Post cerebellum	Frontal Cortex	Parietal Cortex	Caudate Putamen	Corpus Callosum	Hippo. Gyrus	Cerebellum	Ext.Germ. Layer
MATERNAL DOSAGE GROUP I			0 (VEHICLE) MG/KG/DAY							
2002	1.375	13.2	3.4	1440	1416	2592	278	1080	3888	41
2008	1.213	12.7	3.2	1296	1344	2400	240	1056	3648	36
2036	1.357	12.7	3.2	1224	1368	2640	336	1248	3552	36
2062	1.252	12.5	2.9	1368	1368	2352	240	936	3168	41
2067	1.389	13.0	3.4	1368	1392	2544	384	1080	3696	41
2094	1.335	13.2	3.1	1560	1632	2400	336	1080	3216	36
MEAN	1.320	12.883	3.200	1376.000	1420.000	2488.000	302.333	1080.000	3528.000	38.500
SD	0.071	0.293	0.190	116.262	106.703	119.197	58.821	99.535	282.752	2.739
MATERNAL DOSAGE GROUP IV			3 MG/KG/DAY							
2001	1.335	13.0	3.5	1464	1440	2400	365	984	3456	41
2019	1.289	13.0	3.5	1440	1440	2496	307	912	3312	36
2026	1.240	13.1	3.1	1392	1368	2304	259	888	3360	34
2039	1.250	13.1	3.8	1512	1488	2304	307	912	3312	31
2076	1.267	12.6	4.0	1272	1464	2016	240	864	3216	24
2097	1.208	12.3	3.0	1464	1464	2304	269	888	3264	43
MEAN	1.265	12.850	3.483	1424.000	1444.000	2304.000	291.167	908.000	3320.000	34.833
SD	0.044	0.327	0.387	84.057	41.338	160.639	44.937	41.338**	82.675	6.911
MATERNAL DOSAGE GROUP V			10 MG/KG/DAY							
2010	1.356	13.0	3.2	1608	1584	2640	528	1152	3504	36
2020	1.194	13.0	3.0	1584	1464	2688	317	984	3168	41
2028	1.249	12.7	2.2	1080	1296	2544	557	1200	3120	36
2037	1.353	13.0	3.5	1344	1512	2400	307	1032	3792	36
2041	1.289	13.0	3.2	1080	1440	2304	298	1104	3216	41
2043	1.321	13.0	2.9	1080	1488	2448	365	1296	3744	41
MEAN	1.294	12.950	3.000	1296.000	1464.000	2504.000	395.333	1128.000	3424.000	38.500
SD	0.063	0.122	0.443	253.992	96.000	146.904	116.678	113.589	298.476	2.739

PROTOCOL 1613-002: A NEUROBEHAVIORAL DEVELOPMENTAL STUDY OF AMMONIUM PERCHLORATE ADMINISTERED ORALLY IN DRINKING WATER TO RATS
(SPONSOR'S STUDY NUMBER: 7757A210-1096-25F)

MORPHOMETRIC DATA - DAY 12 - F1 GENERATION FEMALE RATS - SUBSET 1

Rat Number	Brain Weight	Ant/Post cerebrum	Ant/Post cerebellum	Frontal Cortex	Parietal Cortex	Caudate Putamen	Corpus Callosum	Hippo. Gyrus	Cerebellum	Ext.Germ. Layer
MATERNAL DOSAGE GROUP I			0 (VEHICLE) MG/KG/DAY							
2122	1.233	12.6	3.0	1224	1344	2208	192	912	3120	43
2136	1.365	12.8	3.5	1512	1440	2448	259	1056	3696	36
2170	1.342	12.9	3.0	1584	1512	2304	288	1104	3600	41
2172	1.517	13.5	3.0	1632	1536	2496	298	1128	3984	41
2185	1.321	12.5	3.2	1416	1296	2208	269	1152	3552	48
2194	1.280	12.5	2.9	1536	1488	2304	336	960	3552	41
MEAN	1.343	12.800	3.100	1484.000	1436.000	2328.000	273.667	1052.000	3584.000	41.667
SD	0.097	0.379	0.219	146.708	96.499	120.479	48.144	96.499	279.336	3.882
MATERNAL DOSAGE GROUP IV			3 MG/KG/DAY							
2132	1.259	12.6	4.0	1440	1392	2304	259	984	3360	48
2133	1.168	12.3	3.7	1440	1392	2160	269	840	3072	46
2145	1.419	13.2	3.3	1560	1656	2256	288	1008	3840	41
2151	1.212	12.8	3.5	1488	1416	2016	269	1080	3456	41
2165	1.222	12.5	3.3	1488	1488	2064	259	912	3360	41
2174	1.347	13.2	4.1	1440	1392	2160	250	960	3696	43
MEAN	1.271	12.767	3.650	1476.000	1456.000	2160.000	265.667	964.000	3464.000	43.333
SD	0.094	0.372	0.345**	47.396	104.797	109.457*	13.079	82.326	272.235	3.011
MATERNAL DOSAGE GROUP V			10 MG/KG/DAY							
2123	1.278	12.4	3.4	1344	1392	2304	307	1080	3024	41
2124	1.310	12.9	3.0	1296	1440	2400	336	1032	3552	36
2140	1.182	12.6	3.0	1464	1464	2352	355	1056	3264	36
2143	1.254	12.9	3.0	2198	1440	2448	346	1008	3168	36
2193	1.314	12.6	2.9	1392	1512	2256	355	936	3696	41
2198	1.330	13.2	3.3	1632	1608	2352	326	1008	3504	41
MEAN	1.278	12.767	3.100	1554.333	1476.000	2352.000	337.500	1020.000	3368.000	38.500
SD	0.054	0.288	0.200	336.401	75.514	67.882	18.706*	49.767	256.549	2.739