

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS

Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

F1_R2

C Number: C99007B
Lock Date: 08/07/2006
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL
Study Gender: Both
TDMSE Version: 2.0.0

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Goldenseal root powder

MALE RATS

Organ

Adrenal Cortex

Adrenal Medulla

Brain

Heart

Kidney

Liver

Liver: Hepatocyte

Lung

Lung: Alveolar Epithelium

Lymph Node, Mesenteric

Mesentery

Nose

Nose: Respiratory Epithelium

Pancreas: Acinus

Pituitary Gland: Pars Distalis

Preputial Gland

Prostate: Epithelium

Skin: Epidermis

Spleen

Morphology

Accessory Adrenal Cortical Nodule

Hyperplasia

Hyperplasia

Compression

Cardiomyopathy

Infarct

Nephropathy

Basophilic Focus

Clear Cell Focus

Eosinophilic Focus

Hemorrhage

Hepatodiaphragmatic Nodule

Mixed Cell Focus

Degeneration

Hypertrophy

Infiltration Cellular Histiocyte

Inflammation Chronic

Metaplasia Osseous

Hyperplasia

Hyperplasia Lymphoid

Accessory Spleen

Inflammation Chronic

Metaplasia

Hyperplasia Focal

Cyst

Hyperplasia Focal

Inflammation Chronic

Hyperplasia

Hyperplasia

Hematopoietic Cell Proliferation

Infiltration Cellular Mixed Cell

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Goldenseal root powder

Stomach, Glandular
Stomach, Glandular: Epithelium
Thymus

Necrosis
Ulcer
Hyperplasia
Atrophy

FEMALE RATS

Organ

Adrenal Cortex

Adrenal Medulla
Bone Marrow

Brain
Clitoral Gland

Harderian Gland

Heart
Kidney
Liver

Liver: Bile Duct
Liver: Hepatocyte

Lung
Lymph Node, Mesenteric
Lymph Node: Mediastinal
Mammary Gland
Mesentery
Mesentery: Fat

Morphology

Accessory Adrenal Cortical Nodule
Hypertrophy Focal
Hyperplasia
Hyperplasia
Infiltration Cellular Histiocyte
Myelofibrosis
Compression
Hyperplasia Focal
Inflammation Chronic
Hyperplasia Focal
Inflammation Chronic
Cardiomyopathy
Nephropathy
Basophilic Focus
Clear Cell Focus
Eosinophilic Focus
Hepatodiaphragmatic Nodule
Mixed Cell Focus
Hyperplasia
Degeneration
Hypertrophy
Hemorrhage
Hyperplasia Lymphoid
Hemorrhage
Hyperplasia
Accessory Spleen
Necrosis

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SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS IN THE ANALYSIS OF Goldenseal root powder

Pancreas
Pituitary Gland: Pars Distalis

Pituitary Gland: Pars Intermedia
Salivary Glands
Spleen

Thyroid Gland: C-Cell

Cyst
Cyst
Hyperplasia Focal
Cyst
Atrophy
Accessory Spleen
Infiltration Cellular Mixed Cell
Hyperplasia

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

OVERALL (a)	17/50 (34%)	7/50 (14%)	14/50 (28%)	19/50 (38%)
POLY-3 RATE (b)	17/44.31	7/41.89	14/44.50	19/44.02
POLY-3 PERCENT (g)	38.4%	16.7%	31.5%	43.2%
TERMINAL (d)	12/33 (36%)	4/29 (14%)	9/30 (30%)	10/25 (40%)
FIRST INCIDENCE	563	663	618	208

STATISTICAL TESTS

POLY 3	P=0.081	P=0.020N*	P=0.322N	P=0.403
POLY 1.5	P=0.082	P=0.017N*	P=0.325N	P=0.419
POLY 6	P=0.074	P=0.025N*	P=0.326N	P=0.361
COCH-ARM / FISHERS	P=0.080	P=0.017N*	P=0.333N	P=0.418
MAX-ISO-POLY-3	P=0.091	P=0.012N*	P=0.247N	P=0.321

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
Angiectasis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.40	0/40.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Degeneration Fatty**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	1/41.55	0/43.40	0/40.10
POLY-3 PERCENT (g)	0%	2.4%	0%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.576N	P=0.496	(e)	(e)
POLY 1.5	P=0.575N	P=0.498	(e)	(e)
POLY 6	P=0.579N	P=0.493	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.403N	P=0.158	(e)	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hyperplasia**

LESION RATES

OVERALL (a)	10/50 (20%)	2/50 (4%)	5/50 (10%)	7/50 (14%)
POLY-3 RATE (b)	10/43.84	2/41.55	5/43.74	7/41.34
POLY-3 PERCENT (g)	22.8%	4.8%	11.4%	16.9%
TERMINAL (d)	5/33 (15%)	2/29 (7%)	4/30 (13%)	4/25 (16%)
FIRST INCIDENCE	571	729 (T)	635	478

STATISTICAL TESTS

POLY 3	P=0.522	P=0.016N*	P=0.128N	P=0.342N
POLY 1.5	P=0.527	P=0.015N*	P=0.128N	P=0.323N
POLY 6	P=0.513	P=0.020N*	P=0.134N	P=0.376N
COCH-ARM / FISHERS	P=0.536	P=0.014N*	P=0.131N	P=0.298N
MAX-ISO-POLY-3	P=0.100N	P=0.008N**	P=0.077N	P=0.255N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	3/42.53	2/41.55	4/43.40	2/41.33
POLY-3 PERCENT (g)	7.1%	4.8%	9.2%	4.8%
TERMINAL (d)	2/33 (6%)	2/29 (7%)	4/30 (13%)	0/25 (0%)
FIRST INCIDENCE	663	729 (T)	729 (T)	451

STATISTICAL TESTS

POLY 3	P=0.488N	P=0.511N	P=0.511	P=0.513N
POLY 1.5	P=0.484N	P=0.505N	P=0.507	P=0.508N
POLY 6	P=0.497N	P=0.521N	P=0.510	P=0.525N
COCH-ARM / FISHERS	P=0.478N	P=0.500N	P=0.500	P=0.500N
MAX-ISO-POLY-3	P=0.543N	P=0.334N	P=0.358	P=0.337N

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 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/42.70	1/41.55	1/43.40	1/40.10
POLY-3 PERCENT (g)	4.7%	2.4%	2.3%	2.5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	1/30 (3%)	1/25 (4%)
FIRST INCIDENCE	611	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.489N	P=0.510N	P=0.494N	P=0.522N
POLY 1.5	P=0.484N	P=0.505N	P=0.496N	P=0.513N
POLY 6	P=0.495N	P=0.518N	P=0.496N	P=0.537N
COCH-ARM / FISHERS	P=0.477N	P=0.500N	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.449N	P=0.291N	P=0.277N	P=0.304N

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/42.83	0/41.55	1/43.42	1/40.51
POLY-3 PERCENT (g)	2.3%	0%	2.3%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	561	---	724	612

STATISTICAL TESTS

POLY 3	P=0.529	P=0.506N	P=0.758N	P=0.748
POLY 1.5	P=0.534	P=0.503N	P=0.759N	P=0.753
POLY 6	P=0.522	P=0.511N	P=0.759N	P=0.741
COCH-ARM / FISHERS	P=0.542	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.532	P=0.166N	P=0.495N	P=0.484

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Vacuolization Cytoplasmic Focal**

LESION RATES

OVERALL (a)	2/50 (4%)	6/50 (12%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/42.29	6/42.91	3/43.55	4/40.46
POLY-3 PERCENT (g)	4.7%	14%	6.9%	9.9%
TERMINAL (d)	2/33 (6%)	3/29 (10%)	2/30 (7%)	3/25 (12%)
FIRST INCIDENCE	729 (T)	530	690	630

STATISTICAL TESTS

POLY 3	P=0.488	P=0.136	P=0.513	P=0.316
POLY 1.5	P=0.500	P=0.135	P=0.508	P=0.324
POLY 6	P=0.469	P=0.136	P=0.516	P=0.303
COCH-ARM / FISHERS	P=0.519	P=0.134	P=0.500	P=0.339
MAX-ISO-POLY-3	P=0.319	P=0.072	P=0.337	P=0.189

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	5/49 (10%)	10/49 (20%)	14/50 (28%)	9/48 (19%)
POLY-3 RATE (b)	5/41.80	10/41.03	14/44.48	9/40.09
POLY-3 PERCENT (g)	12%	24.4%	31.5%	22.5%
TERMINAL (d)	4/33 (12%)	7/28 (25%)	10/30 (33%)	5/25 (20%)
FIRST INCIDENCE	716	666	556	478

STATISTICAL TESTS

POLY 3	P=0.297	P=0.117	P=0.024*	P=0.165
POLY 1.5	P=0.304	P=0.122	P=0.023*	P=0.171
POLY 6	P=0.280	P=0.108	P=0.025*	P=0.155
COCH-ARM / FISHERS	P=0.321	P=0.131	P=0.022*	P=0.182
MAX-ISO-POLY-3	P=0.082	P=0.071	P=0.014*	P=0.105

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	4/49 (8%)	4/50 (8%)	4/50 (8%)	8/50 (16%)
POLY-3 RATE (b)	4/43.39	4/42.05	4/44.20	8/43.03
POLY-3 PERCENT (g)	9.2%	9.5%	9.1%	18.6%
TERMINAL (d)	2/33 (6%)	3/29 (10%)	2/30 (7%)	2/25 (8%)
FIRST INCIDENCE	422	576	594	450

STATISTICAL TESTS

POLY 3	P=0.089	P=0.627	P=0.633N	P=0.171
POLY 1.5	P=0.090	P=0.637	P=0.634N	P=0.176
POLY 6	P=0.087	P=0.612	P=0.635N	P=0.163
COCH-ARM / FISHERS	P=0.093	P=0.631N	P=0.631N	P=0.188
MAX-ISO-POLY-3	P=0.141	P=0.481	P=0.488N	P=0.105

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.04	0/41.55	2/43.40	0/40.10
POLY-3 PERCENT (g)	0%	0%	4.6%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	2/30 (7%)	0/25 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.713	(e)	P=0.244	(e)
POLY 1.5	P=0.719N	(e)	P=0.243	(e)
POLY 6	P=0.697	(e)	P=0.243	(e)
COCH-ARM / FISHERS	P=0.707N	(e)	P=0.253	(e)
MAX-ISO-POLY-3	P=0.270	(e)	P=0.081	(e)

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Myelofibrosis**

LESION RATES

OVERALL (a)	2/49 (4%)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/42.97	2/41.84	0/43.40	3/40.27
POLY-3 PERCENT (g)	4.7%	4.8%	0%	7.5%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	2/25 (8%)
FIRST INCIDENCE	583	649	---	684

STATISTICAL TESTS

POLY 3	P=0.356	P=0.685	P=0.235N	P=0.470
POLY 1.5	P=0.364	P=0.692	P=0.234N	P=0.486
POLY 6	P=0.345	P=0.674	P=0.238N	P=0.448
COCH-ARM / FISHERS	P=0.376	P=0.684N	P=0.242N	P=0.510
MAX-ISO-POLY-3	P=0.278	P=0.488	P=0.075N	P=0.304

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Compression**

LESION RATES

OVERALL (a)	2/49 (4%)	10/50 (20%)	3/50 (6%)	4/50 (8%)
POLY-3 RATE (b)	2/42.20	10/43.65	3/43.92	4/40.57
POLY-3 PERCENT (g)	4.7%	22.9%	6.8%	9.9%
TERMINAL (d)	0/32 (0%)	3/29 (10%)	0/30 (0%)	3/25 (12%)
FIRST INCIDENCE	407	437	659	590

STATISTICAL TESTS

POLY 3	P=0.424N	P=0.015*	P=0.518	P=0.318
POLY 1.5	P=0.409N	P=0.015*	P=0.514	P=0.329
POLY 6	P=0.445N	P=0.015*	P=0.522	P=0.303
COCH-ARM / FISHERS	P=0.386N	P=0.015*	P=0.510	P=0.349
MAX-ISO-POLY-3	P=0.183	P=0.007**	P=0.342	P=0.191

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Hemorrhage**

LESION RATES

OVERALL (a)	2/49 (4%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/42.87	4/42.29	2/43.86	1/40.10
POLY-3 PERCENT (g)	4.7%	9.5%	4.6%	2.5%
TERMINAL (d)	0/32 (0%)	0/29 (0%)	1/30 (3%)	1/25 (4%)
FIRST INCIDENCE	407	656	594	729 (T)

STATISTICAL TESTS

POLY 3	P=0.262N	P=0.330	P=0.686N	P=0.523N
POLY 1.5	P=0.251N	P=0.336	P=0.687N	P=0.512N
POLY 6	P=0.277N	P=0.325	P=0.686N	P=0.539N
COCH-ARM / FISHERS	P=0.233N	P=0.349	P=0.684N	P=0.492N
MAX-ISO-POLY-3	P=0.307N	P=0.198	P=0.490N	P=0.306N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Necrosis**

LESION RATES

OVERALL (a)	1/49 (2%)	4/50 (8%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/41.80	4/43.21	1/43.42	0/40.10
POLY-3 PERCENT (g)	2.4%	9.3%	2.3%	0%
TERMINAL (d)	0/32 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	575	437	724	---

STATISTICAL TESTS

POLY 3	P=0.134N	P=0.188	P=0.752N	P=0.508N
POLY 1.5	P=0.130N	P=0.188	P=0.754N	P=0.503N
POLY 6	P=0.142N	P=0.186	P=0.753N	P=0.516N
COCH-ARM / FISHERS	P=0.125N	P=0.187	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.131N	P=0.092	P=0.488N	P=0.170N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Epididymis
 Granuloma Sperm**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/42.29	0/41.55	0/43.40	2/40.10
POLY-3 PERCENT (g)	2.4%	0%	0%	5%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	0/30 (0%)	2/25 (8%)
FIRST INCIDENCE	729 (T)	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.189	P=0.504N	P=0.495N	P=0.481
POLY 1.5	P=0.191	P=0.502N	P=0.497N	P=0.489
POLY 6	P=0.186	P=0.507N	P=0.494N	P=0.469
COCH-ARM / FISHERS	P=0.195	P=0.500N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.132	P=0.163N	P=0.158N	P=0.270

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Epididymis
 Inflammation Chronic**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	1/42.29	2/41.55	3/43.86	2/40.10
POLY-3 PERCENT (g)	2.4%	4.8%	6.8%	5%
TERMINAL (d)	1/33 (3%)	2/29 (7%)	2/30 (7%)	2/25 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	594	729 (T)

STATISTICAL TESTS

POLY 3	P=0.457	P=0.494	P=0.318	P=0.481
POLY 1.5	P=0.468	P=0.497	P=0.313	P=0.489
POLY 6	P=0.439	P=0.488	P=0.321	P=0.469
COCH-ARM / FISHERS	P=0.485	P=0.500	P=0.309	P=0.500
MAX-ISO-POLY-3	P=0.376	P=0.277	P=0.168	P=0.270

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Eye
 Cataract**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/42.29	0/41.55	0/43.40	1/40.13
POLY-3 PERCENT (g)	4.7%	0%	0%	2.5%
TERMINAL (d)	2/33 (6%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	---	---	723

STATISTICAL TESTS

POLY 3	P=0.624N	P=0.241N	P=0.231N	P=0.518N
POLY 1.5	P=0.625N	P=0.239N	P=0.234N	P=0.511N
POLY 6	P=0.623N	P=0.244N	P=0.230N	P=0.530N
COCH-ARM / FISHERS	P=0.624N	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.156N	P=0.079N	P=0.076N	P=0.300N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Eye: Retina
 Degeneration

LESION RATES

OVERALL (a)	2/50 (4%)	3/50 (6%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/42.29	3/41.91	1/43.74	2/40.13
POLY-3 PERCENT (g)	4.7%	7.2%	2.3%	5%
TERMINAL (d)	2/33 (6%)	1/29 (3%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	649	635	723

STATISTICAL TESTS

POLY 3	P=0.548N	P=0.496	P=0.488N	P=0.676
POLY 1.5	P=0.541N	P=0.498	P=0.493N	P=0.683
POLY 6	P=0.558N	P=0.492	P=0.485N	P=0.663
COCH-ARM / FISHERS	P=0.530N	P=0.500	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.502N	P=0.320	P=0.273N	P=0.478

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/42.29	0/41.55	1/43.86	1/40.10
POLY-3 PERCENT (g)	2.4%	0%	2.3%	2.5%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	729 (T)	---	594	729 (T)

STATISTICAL TESTS

POLY 3	P=0.527	P=0.504N	P=0.753N	P=0.749
POLY 1.5	P=0.533	P=0.502N	P=0.756N	P=0.754
POLY 6	P=0.519	P=0.507N	P=0.751N	P=0.741
COCH-ARM / FISHERS	P=0.542	P=0.500N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.531	P=0.163N	P=0.489N	P=0.485

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Harderian Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	1/41.55	0/43.40	0/40.10
POLY-3 PERCENT (g)	0%	2.4%	0%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.576N	P=0.496	(e)	(e)
POLY 1.5	P=0.575N	P=0.498	(e)	(e)
POLY 6	P=0.579N	P=0.493	(e)	(e)
COCH-ARM / FISHERS	P=0.572N	P=0.500	(e)	(e)
MAX-ISO-POLY-3	P=0.403N	P=0.158	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	47/50 (94%)	38/50 (76%)	39/50 (78%)	36/50 (72%)
POLY-3 RATE (b)	47/49.48	38/47.67	39/47.80	36/44.88
POLY-3 PERCENT (g)	95%	79.7%	81.6%	80.2%
TERMINAL (d)	31/33 (94%)	24/29 (83%)	25/30 (83%)	22/25 (88%)
FIRST INCIDENCE	407	355	316	208

STATISTICAL TESTS

POLY 3	P=0.096N	P=0.017N*	P=0.030N*	P=0.016N*
POLY 1.5	P=0.053N	P=0.013N*	P=0.024N*	P=0.007N**
POLY 6	P=0.188N	P=0.026N*	P=0.046N*	P=0.054N
COCH-ARM / FISHERS	P=0.025N*	P=0.011N*	P=0.020N*	P=0.003N**
MAX-ISO-POLY-3	P=0.033N*	P=0.008N**	P=0.014N*	P=0.009N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Intestine Large, Cecum
 Edema

LESION RATES

OVERALL (a)	1/49 (2%)	1/50 (2%)	1/48 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.48	1/41.82	1/41.85	2/40.46
POLY-3 PERCENT (g)	2.4%	2.4%	2.4%	4.9%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/29 (0%)	1/25 (4%)
FIRST INCIDENCE	600	656	649	630

STATISTICAL TESTS

POLY 3	P=0.344	P=0.757	P=0.757	P=0.483
POLY 1.5	P=0.352	P=0.761	P=0.757	P=0.492
POLY 6	P=0.333	P=0.752	P=0.757	P=0.469
COCH-ARM / FISHERS	P=0.363	P=0.747N	P=0.747	P=0.508
MAX-ISO-POLY-3	P=0.410	P=0.495	P=0.495	P=0.271

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.29	2/42.39	0/43.40	1/40.10
POLY-3 PERCENT (g)	0%	4.7%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	---	563	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.598	P=0.237	(e)	P=0.489
POLY 1.5	P=0.604	P=0.237	(e)	P=0.494
POLY 6	P=0.588	P=0.236	(e)	P=0.482
COCH-ARM / FISHERS	P=0.613	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.333	P=0.076	(e)	P=0.158

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	0/42.29	0/41.55	3/43.92	2/40.82
POLY-3 PERCENT (g)	0%	0%	6.8%	4.9%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	---	---	649	478

STATISTICAL TESTS

POLY 3	P=0.132	(e)	P=0.125	P=0.229
POLY 1.5	P=0.136	(e)	P=0.123	P=0.232
POLY 6	P=0.125	(e)	P=0.128	P=0.223
COCH-ARM / FISHERS	P=0.143	(e)	P=0.121	P=0.247
MAX-ISO-POLY-3	P=0.096	(e)	P=0.043*	P=0.075

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	46/50 (92%)	49/50 (98%)	46/50 (92%)	49/50 (98%)
POLY-3 RATE (b)	46/47.94	49/49.71	46/47.49	49/49.02
POLY-3 PERCENT (g)	96%	98.6%	96.9%	100%
TERMINAL (d)	33/33 (100%)	29/29 (100%)	30/30 (100%)	25/25 (100%)
FIRST INCIDENCE	407	355	534	450

STATISTICAL TESTS

POLY 3	P=0.165	P=0.410	P=0.661	P=0.179
POLY 1.5	P=0.145	P=0.280	P=0.622	P=0.123
POLY 6	P=0.291	P=0.688	P=0.807	P=0.449
COCH-ARM / FISHERS	P=0.245	P=0.181	P=0.643N	P=0.181
MAX-ISO-POLY-3	P=0.060	P=0.157	P=0.374	P=0.030*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Accumulation, Hyaline Droplet**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	2/43.16	0/41.55	0/43.40	1/40.10
POLY-3 PERCENT (g)	4.6%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	422	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.622N	P=0.245N	P=0.236N	P=0.526N
POLY 1.5	P=0.623N	P=0.242N	P=0.236N	P=0.516N
POLY 6	P=0.619N	P=0.251N	P=0.237N	P=0.541N
COCH-ARM / FISHERS	P=0.624N	P=0.247N	P=0.247N	P=0.500N
MAX-ISO-POLY-3	P=0.165N	P=0.084N	P=0.076N	P=0.308N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/42.34	1/41.78	2/43.52	2/41.44
POLY-3 PERCENT (g)	2.4%	2.4%	4.6%	4.8%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	716	666	703	208

STATISTICAL TESTS

POLY 3	P=0.367	P=0.758	P=0.510	P=0.493
POLY 1.5	P=0.372	P=0.759	P=0.506	P=0.497
POLY 6	P=0.357	P=0.755	P=0.511	P=0.483
COCH-ARM / FISHERS	P=0.374	P=0.753N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.444	P=0.495	P=0.291	P=0.276

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Pigmentation**

LESION RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	3/43.13	1/42.43	4/44.32	4/41.73
POLY-3 PERCENT (g)	7%	2.4%	9%	9.6%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	571	355	534	509

STATISTICAL TESTS

POLY 3	P=0.255	P=0.311N	P=0.515	P=0.482
POLY 1.5	P=0.259	P=0.307N	P=0.509	P=0.489
POLY 6	P=0.251	P=0.320N	P=0.516	P=0.470
COCH-ARM / FISHERS	P=0.269	P=0.309N	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.313	P=0.160N	P=0.362	P=0.333

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	2/41.72	0/43.40	0/40.10
POLY-3 PERCENT (g)	0%	4.8%	0%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	684	---	---

STATISTICAL TESTS

POLY 3	P=0.378N	P=0.234	(e)	(e)
POLY 1.5	P=0.375N	P=0.235	(e)	(e)
POLY 6	P=0.384N	P=0.231	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.271N	P=0.076	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Angiectasis

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	1/41.55	2/44.05	0/40.10
POLY-3 PERCENT (g)	0%	2.4%	4.5%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	635	---

STATISTICAL TESTS

POLY 3	P=0.550N	P=0.496	P=0.246	(e)
POLY 1.5	P=0.542N	P=0.498	P=0.243	(e)
POLY 6	P=0.563N	P=0.493	P=0.249	(e)
COCH-ARM / FISHERS	P=0.530N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.350	P=0.158	P=0.085	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Basophilic Focus

LESION RATES

OVERALL (a)	20/50 (40%)	33/50 (66%)	22/50 (44%)	13/50 (26%)
POLY-3 RATE (b)	20/42.94	33/43.43	22/44.11	13/40.26
POLY-3 PERCENT (g)	46.6%	76%	49.9%	32.3%
TERMINAL (d)	17/33 (52%)	27/29 (93%)	20/30 (67%)	12/25 (48%)
FIRST INCIDENCE	575	517	556	688

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.002**	P=0.462	P=0.128N
POLY 1.5	P=0.003N**	P=0.004**	P=0.446	P=0.115N
POLY 6	P=0.004N**	P<0.001**	P=0.464	P=0.156N
COCH-ARM / FISHERS	P=0.003N**	P=0.008**	P=0.420	P=0.101N
MAX-ISO-POLY-3	P=0.005N**	P<0.001**	P=0.376	P=0.092N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	19/50 (38%)	17/50 (34%)	3/50 (6%)	2/50 (4%)
POLY-3 RATE (b)	19/42.29	17/41.86	3/43.40	2/40.10
POLY-3 PERCENT (g)	44.9%	40.6%	6.9%	5%
TERMINAL (d)	19/33 (58%)	16/29 (55%)	3/30 (10%)	2/25 (8%)
FIRST INCIDENCE	729 (T)	642	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.427N	P<0.001N**	P<0.001N**
POLY 1.5	P<0.001N**	P=0.422N	P<0.001N**	P<0.001N**
POLY 6	P<0.001N**	P=0.442N	P<0.001N**	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.418N	P<0.001N**	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.341N	P<0.001N**	P<0.001N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Degeneration Cystic

LESION RATES

OVERALL (a)	6/50 (12%)	4/50 (8%)	4/50 (8%)	7/50 (14%)
POLY-3 RATE (b)	6/43.27	4/41.92	4/43.84	7/40.63
POLY-3 PERCENT (g)	13.9%	9.5%	9.1%	17.2%
TERMINAL (d)	3/33 (9%)	2/29 (7%)	2/30 (7%)	4/25 (16%)
FIRST INCIDENCE	583	678	635	653

STATISTICAL TESTS

POLY 3	P=0.279	P=0.389N	P=0.361N	P=0.451
POLY 1.5	P=0.291	P=0.380N	P=0.364N	P=0.471
POLY 6	P=0.262	P=0.404N	P=0.363N	P=0.421
COCH-ARM / FISHERS	P=0.310	P=0.370N	P=0.370N	P=0.500
MAX-ISO-POLY-3	P=0.319	P=0.272N	P=0.246N	P=0.340

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Eosinophilic Focus

LESION RATES

OVERALL (a)	4/50 (8%)	5/50 (10%)	25/50 (50%)	28/50 (56%)
POLY-3 RATE (b)	4/42.29	5/42.14	25/45.03	28/41.86
POLY-3 PERCENT (g)	9.5%	11.9%	55.5%	66.9%
TERMINAL (d)	4/33 (12%)	2/29 (7%)	19/30 (63%)	22/25 (88%)
FIRST INCIDENCE	729 (T)	656	534	451

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.498	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.499	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.496	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.360	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hemorrhage

LESION RATES

OVERALL (a)	1/50 (2%)	6/50 (12%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/42.29	6/42.45	0/43.40	0/40.10
POLY-3 PERCENT (g)	2.4%	14.1%	0%	0%
TERMINAL (d)	1/33 (3%)	4/29 (14%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	506	---	---

STATISTICAL TESTS

POLY 3	P=0.060N	P=0.055	P=0.495N	P=0.511N
POLY 1.5	P=0.059N	P=0.056	P=0.497N	P=0.506N
POLY 6	P=0.063N	P=0.054	P=0.494N	P=0.518N
COCH-ARM / FISHERS	P=0.061N	P=0.056	P=0.500N	P=0.500N
MAX-ISO-POLY-3	P=0.050N*	P=0.023*	P=0.158N	P=0.172N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hepatodiaphragmatic Nodule

LESION RATES

OVERALL (a)	3/50 (6%)	13/50 (26%)	6/50 (12%)	2/50 (4%)
POLY-3 RATE (b)	3/42.75	13/42.44	6/44.25	2/40.10
POLY-3 PERCENT (g)	7%	30.6%	13.6%	5%
TERMINAL (d)	2/33 (6%)	10/29 (35%)	3/30 (10%)	2/25 (8%)
FIRST INCIDENCE	593	632	644	729 (T)

STATISTICAL TESTS

POLY 3	P=0.064N	P=0.004**	P=0.258	P=0.529N
POLY 1.5	P=0.058N	P=0.005**	P=0.252	P=0.517N
POLY 6	P=0.075N	P=0.004**	P=0.264	P=0.549N
COCH-ARM / FISHERS	P=0.055N	P=0.006**	P=0.243	P=0.500N
MAX-ISO-POLY-3	P=0.060N	P=0.002**	P=0.163	P=0.353N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	4/50 (8%)	6/50 (12%)	6/50 (12%)	6/50 (12%)
POLY-3 RATE (b)	4/42.29	6/41.57	6/43.40	6/40.17
POLY-3 PERCENT (g)	9.5%	14.4%	13.8%	14.9%
TERMINAL (d)	4/33 (12%)	5/29 (17%)	6/30 (20%)	5/25 (20%)
FIRST INCIDENCE	729 (T)	723	729 (T)	711

STATISTICAL TESTS

POLY 3	P=0.364	P=0.358	P=0.385	P=0.336
POLY 1.5	P=0.379	P=0.364	P=0.380	P=0.349
POLY 6	P=0.340	P=0.346	P=0.386	P=0.315
COCH-ARM / FISHERS	P=0.403	P=0.370	P=0.370	P=0.370
MAX-ISO-POLY-3	P=0.387	P=0.244	P=0.268	P=0.230

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	9/50 (18%)	21/50 (42%)	13/50 (26%)	7/50 (14%)
POLY-3 RATE (b)	9/42.38	21/41.99	13/43.79	7/41.46
POLY-3 PERCENT (g)	21.2%	50%	29.7%	16.9%
TERMINAL (d)	8/33 (24%)	19/29 (66%)	12/30 (40%)	3/25 (12%)
FIRST INCIDENCE	706	642	618	523

STATISTICAL TESTS

POLY 3	P=0.042N*	P=0.004**	P=0.256	P=0.409N
POLY 1.5	P=0.043N*	P=0.005**	P=0.247	P=0.404N
POLY 6	P=0.043N*	P=0.003**	P=0.259	P=0.420N
COCH-ARM / FISHERS	P=0.046N*	P=0.008**	P=0.235	P=0.393N
MAX-ISO-POLY-3	P=0.044N*	P=0.002**	P=0.187	P=0.308N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.83	2/41.84	1/43.86	2/40.82
POLY-3 PERCENT (g)	2.3%	4.8%	2.3%	4.9%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	561	649	594	478

STATISTICAL TESTS

POLY 3	P=0.457	P=0.492	P=0.756N	P=0.483
POLY 1.5	P=0.464	P=0.496	P=0.757N	P=0.490
POLY 6	P=0.445	P=0.485	P=0.755N	P=0.471
COCH-ARM / FISHERS	P=0.474	P=0.500	P=0.753N	P=0.500
MAX-ISO-POLY-3	P=0.436	P=0.275	P=0.493N	P=0.271

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Bile Duct
 Hyperplasia

LESION RATES

OVERALL (a)	43/50 (86%)	38/50 (76%)	45/50 (90%)	39/50 (78%)
POLY-3 RATE (b)	43/46.98	38/46.20	45/47.53	39/45.09
POLY-3 PERCENT (g)	91.5%	82.2%	94.7%	86.5%
TERMINAL (d)	31/33 (94%)	24/29 (83%)	30/30 (100%)	22/25 (88%)
FIRST INCIDENCE	501	355	431	478

STATISTICAL TESTS

POLY 3	P=0.478N	P=0.133N	P=0.411	P=0.311N
POLY 1.5	P=0.418N	P=0.129N	P=0.402	P=0.266N
POLY 6	P=0.568N	P=0.159N	P=0.374	P=0.402N
COCH-ARM / FISHERS	P=0.320N	P=0.154N	P=0.380	P=0.218N
MAX-ISO-POLY-3	P=0.326N	P=0.075N	P=0.246	P=0.198N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Centrilobular
 Necrosis

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.29	2/42.86	0/43.40	1/40.17
POLY-3 PERCENT (g)	0%	4.7%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	506	---	711

STATISTICAL TESTS

POLY 3	P=0.599	P=0.240	(e)	P=0.490
POLY 1.5	P=0.604	P=0.239	(e)	P=0.494
POLY 6	P=0.590	P=0.239	(e)	P=0.483
COCH-ARM / FISHERS	P=0.613	P=0.247	(e)	P=0.500
MAX-ISO-POLY-3	P=0.333	P=0.079	(e)	P=0.158

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver: Hepatocyte
 Degeneration**

LESION RATES

OVERALL (a)	0/50 (0%)	22/50 (44%)	30/50 (60%)	19/50 (38%)
POLY-3 RATE (b)	0/42.29	22/41.99	30/44.61	19/41.23
POLY-3 PERCENT (g)	0%	52.4%	67.3%	46.1%
TERMINAL (d)	0/33 (0%)	20/29 (69%)	26/30 (87%)	16/25 (64%)
FIRST INCIDENCE	---	642	556	523

STATISTICAL TESTS

POLY 3	P=0.002**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P=0.003**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.013*	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Hepatocyte
 Hypertrophy

LESION RATES

OVERALL (a)	0/50 (0%)	19/50 (38%)	31/50 (62%)	27/50 (54%)
POLY-3 RATE (b)	0/42.29	19/41.55	31/45.04	27/43.45
POLY-3 PERCENT (g)	0%	45.7%	68.8%	62.1%
TERMINAL (d)	0/33 (0%)	19/29 (66%)	27/30 (90%)	19/25 (76%)
FIRST INCIDENCE	---	729 (T)	556	450

STATISTICAL TESTS

POLY 3	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P<0.001**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/42.53	4/43.39	2/43.79	1/40.51
POLY-3 PERCENT (g)	4.7%	9.2%	4.6%	2.5%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	663	355	618	612

STATISTICAL TESTS

POLY 3	P=0.256N	P=0.346	P=0.684N	P=0.517N
POLY 1.5	P=0.249N	P=0.344	P=0.687N	P=0.510N
POLY 6	P=0.267N	P=0.345	P=0.683N	P=0.528N
COCH-ARM / FISHERS	P=0.237N	P=0.339	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.306N	P=0.209	P=0.487N	P=0.299N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver: Kupffer Cell
 Pigmentation**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	3/50 (6%)
POLY-3 RATE (b)	2/42.81	0/41.55	2/43.71	3/40.96
POLY-3 PERCENT (g)	4.7%	0%	4.6%	7.3%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	571	---	649	627

STATISTICAL TESTS

POLY 3	P=0.201	P=0.244N	P=0.687N	P=0.480
POLY 1.5	P=0.204	P=0.241N	P=0.689N	P=0.487
POLY 6	P=0.198	P=0.249N	P=0.686N	P=0.469
COCH-ARM / FISHERS	P=0.210	P=0.247N	P=0.691N	P=0.500
MAX-ISO-POLY-3	P=0.218	P=0.082N	P=0.491N	P=0.309

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Hemorrhage**

LESION RATES

OVERALL (a)	1/50 (2%)	4/50 (8%)	4/50 (8%)	4/50 (8%)
POLY-3 RATE (b)	1/43.11	4/42.36	4/44.01	4/40.10
POLY-3 PERCENT (g)	2.3%	9.4%	9.1%	10%
TERMINAL (d)	0/33 (0%)	2/29 (7%)	2/30 (7%)	4/25 (16%)
FIRST INCIDENCE	407	576	594	729 (T)

STATISTICAL TESTS

POLY 3	P=0.238	P=0.173	P=0.184	P=0.156
POLY 1.5	P=0.254	P=0.175	P=0.182	P=0.165
POLY 6	P=0.217	P=0.169	P=0.186	P=0.145
COCH-ARM / FISHERS	P=0.279	P=0.181	P=0.181	P=0.181
MAX-ISO-POLY-3	P=0.170	P=0.081	P=0.089	P=0.077

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	34/50 (68%)	24/50 (48%)	25/50 (50%)	24/50 (48%)
POLY-3 RATE (b)	34/45.71	24/45.47	25/45.54	24/43.05
POLY-3 PERCENT (g)	74.4%	52.8%	54.9%	55.8%
TERMINAL (d)	26/33 (79%)	13/29 (45%)	17/30 (57%)	16/25 (64%)
FIRST INCIDENCE	407	506	431	509

STATISTICAL TESTS

POLY 3	P=0.153N	P=0.021N*	P=0.034N*	P=0.042N*
POLY 1.5	P=0.133N	P=0.025N*	P=0.040N*	P=0.038N*
POLY 6	P=0.192N	P=0.017N*	P=0.032N*	P=0.053N
COCH-ARM / FISHERS	P=0.107N	P=0.034N*	P=0.052N	P=0.034N*
MAX-ISO-POLY-3	P=0.043N*	P=0.012N*	P=0.020N*	P=0.028N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	16/50 (32%)	10/50 (20%)	17/50 (34%)	3/50 (6%)
POLY-3 RATE (b)	16/43.11	10/43.00	17/43.95	3/40.73
POLY-3 PERCENT (g)	37.1%	23.3%	38.7%	7.4%
TERMINAL (d)	15/33 (46%)	6/29 (21%)	16/30 (53%)	2/25 (8%)
FIRST INCIDENCE	407	509	556	523

STATISTICAL TESTS

POLY 3	P=0.003N**	P=0.118N	P=0.528	P<0.001N**
POLY 1.5	P=0.003N**	P=0.122N	P=0.515	P<0.001N**
POLY 6	P=0.004N**	P=0.113N	P=0.536	P<0.001N**
COCH-ARM / FISHERS	P=0.003N**	P=0.127N	P=0.500	P<0.001N**
MAX-ISO-POLY-3	P=0.002N**	P=0.077N	P=0.438	P<0.001N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	5/50 (10%)	3/50 (6%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	5/42.80	3/41.55	0/43.40	1/40.20
POLY-3 PERCENT (g)	11.7%	7.2%	0%	2.5%
TERMINAL (d)	3/33 (9%)	3/29 (10%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	600	729 (T)	---	703

STATISTICAL TESTS

POLY 3	P=0.073N	P=0.372N	P=0.029N*	P=0.115N
POLY 1.5	P=0.073N	P=0.365N	P=0.030N*	P=0.110N
POLY 6	P=0.075N	P=0.386N	P=0.029N*	P=0.125N
COCH-ARM / FISHERS	P=0.072N	P=0.357N	P=0.028N*	P=0.102N
MAX-ISO-POLY-3	P=0.031N*	P=0.247N	P=0.009N**	P=0.057N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	8/50 (16%)	3/50 (6%)	3/50 (6%)	8/50 (16%)
POLY-3 RATE (b)	8/42.29	3/41.94	3/43.40	8/41.60
POLY-3 PERCENT (g)	18.9%	7.2%	6.9%	19.2%
TERMINAL (d)	8/33 (24%)	1/29 (3%)	3/30 (10%)	4/25 (16%)
FIRST INCIDENCE	729 (T)	642	729 (T)	523

STATISTICAL TESTS

POLY 3	P=0.273	P=0.098N	P=0.088N	P=0.595
POLY 1.5	P=0.275	P=0.099N	P=0.093N	P=0.598
POLY 6	P=0.269	P=0.100N	P=0.086N	P=0.588
COCH-ARM / FISHERS	P=0.283	P=0.100N	P=0.100N	P=0.607N
MAX-ISO-POLY-3	P=0.212	P=0.053N	P=0.049N*	P=0.485

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric
 Ectasia**

LESION RATES

OVERALL (a)	2/49 (4%)	1/49 (2%)	4/50 (8%)	2/50 (4%)
POLY-3 RATE (b)	2/42.16	1/41.21	4/43.55	2/40.10
POLY-3 PERCENT (g)	4.7%	2.4%	9.2%	5%
TERMINAL (d)	1/33 (3%)	1/29 (3%)	3/30 (10%)	2/25 (8%)
FIRST INCIDENCE	716	729 (T)	690	729 (T)

STATISTICAL TESTS

POLY 3	P=0.503	P=0.508N	P=0.352	P=0.676
POLY 1.5	P=0.518	P=0.505N	P=0.349	P=0.686
POLY 6	P=0.483	P=0.514N	P=0.352	P=0.662
COCH-ARM / FISHERS	P=0.542	P=0.500N	P=0.349	P=0.684N
MAX-ISO-POLY-3	P=0.397	P=0.289N	P=0.214	P=0.479

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	0/49 (0%)	2/49 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/42.11	2/42.16	2/43.86	1/40.68
POLY-3 PERCENT (g)	0%	4.7%	4.6%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	517	594	547

STATISTICAL TESTS

POLY 3	P=0.576	P=0.237	P=0.246	P=0.493
POLY 1.5	P=0.586	P=0.237	P=0.244	P=0.497
POLY 6	P=0.561	P=0.236	P=0.247	P=0.487
COCH-ARM / FISHERS	P=0.604	P=0.247	P=0.253	P=0.505
MAX-ISO-POLY-3	P=0.249	P=0.076	P=0.083	P=0.160

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	4/49 (8%)	11/49 (22%)	9/50 (18%)	8/50 (16%)
POLY-3 RATE (b)	4/42.52	11/44.59	9/44.84	8/43.58
POLY-3 PERCENT (g)	9.4%	24.7%	20.1%	18.4%
TERMINAL (d)	3/33 (9%)	5/29 (17%)	5/30 (17%)	3/25 (12%)
FIRST INCIDENCE	611	437	556	208

STATISTICAL TESTS

POLY 3	P=0.432	P=0.052	P=0.135	P=0.187
POLY 1.5	P=0.440	P=0.049*	P=0.130	P=0.189
POLY 6	P=0.410	P=0.055	P=0.140	P=0.177
COCH-ARM / FISHERS	P=0.441	P=0.045*	P=0.125	P=0.188
MAX-ISO-POLY-3	P=0.134	P=0.031*	P=0.084	P=0.116

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Mediastinal
 Ectasia

LESION RATES

OVERALL (a)	1/11 (9%)	0/11 (0%)	2/14 (14%)	1/19 (5%)
POLY-3 RATE (b)	1/7.82	0/8.73	2/11.07	1/15.66
POLY-3 PERCENT (g)	12.8%	0%	18.1%	6.4%
TERMINAL (d)	0/3 (0%)	0/3 (0%)	1/4 (25%)	1/9 (11%)
FIRST INCIDENCE	563	---	649	729 (T)

STATISTICAL TESTS

POLY 3	P=0.572N	P=0.478N	P=0.625	P=0.598N
POLY 1.5	P=0.585N	P=0.487N	P=0.603	P=0.615N
POLY 6	P=0.546N	P=0.470N	P=0.658	P=0.573N
COCH-ARM / FISHERS	P=0.598N	P=0.500N	P=0.593	P=0.607N
MAX-ISO-POLY-3	P=0.539N	P=0.154N	P=0.392	P=0.336N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Mediastinal Hemorrhage

LESION RATES

OVERALL (a)	1/11 (9%)	2/11 (18%)	1/14 (7%)	1/19 (5%)
POLY-3 RATE (b)	1/7.74	2/8.98	1/10.77	1/15.66
POLY-3 PERCENT (g)	12.9%	22.3%	9.3%	6.4%
TERMINAL (d)	0/3 (0%)	1/3 (33%)	1/4 (25%)	1/9 (11%)
FIRST INCIDENCE	593	663	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.290N	P=0.555	P=0.688N	P=0.595N
POLY 1.5	P=0.309N	P=0.531	P=0.699N	P=0.614N
POLY 6	P=0.264N	P=0.581	P=0.674N	P=0.570N
COCH-ARM / FISHERS	P=0.330N	P=0.500	P=0.697N	P=0.607N
MAX-ISO-POLY-3	P=0.410N	P=0.326	P=0.412N	P=0.334N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node: Mediastinal
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	3/11 (27%)	1/11 (9%)	2/14 (14%)	3/19 (16%)
POLY-3 RATE (b)	3/8.95	1/8.98	2/10.77	3/16.17
POLY-3 PERCENT (g)	33.5%	11.1%	18.6%	18.6%
TERMINAL (d)	0/3 (0%)	0/3 (0%)	2/4 (50%)	2/9 (22%)
FIRST INCIDENCE	501	663	729 (T)	572

STATISTICAL TESTS

POLY 3	P=0.474N	P=0.284N	P=0.406N	P=0.363N
POLY 1.5	P=0.489N	P=0.287N	P=0.400N	P=0.377N
POLY 6	P=0.444N	P=0.288N	P=0.416N	P=0.345N
COCH-ARM / FISHERS	P=0.504N	P=0.293N	P=0.378N	P=0.380N
MAX-ISO-POLY-3	P=0.308N	P=0.128N	P=0.232N	P=0.234N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node: Mediastinal
 Pigmentation**

LESION RATES

OVERALL (a)	0/11 (0%)	1/11 (9%)	0/14 (0%)	1/19 (5%)
POLY-3 RATE (b)	0/7.28	1/8.73	0/10.77	1/15.66
POLY-3 PERCENT (g)	0%	11.5%	0%	6.4%
TERMINAL (d)	0/3 (0%)	1/3 (33%)	0/4 (0%)	1/9 (11%)
FIRST INCIDENCE	---	729 (T)	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.641	P=0.536	(e)	P=0.647
POLY 1.5	P=0.615	P=0.520	(e)	P=0.629
POLY 6	P=0.678	P=0.556	(e)	P=0.672
COCH-ARM / FISHERS	P=0.585	P=0.500	(e)	P=0.633
MAX-ISO-POLY-3	P=0.481	P=0.200	(e)	P=0.294

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Pancreatic Hemorrhage

LESION RATES

OVERALL (a)	1/11 (9%)	0/11 (0%)	1/14 (7%)	1/19 (5%)
POLY-3 RATE (b)	1/7.28	0/8.73	1/10.77	1/15.66
POLY-3 PERCENT (g)	13.7%	0%	9.3%	6.4%
TERMINAL (d)	1/3 (33%)	0/3 (0%)	1/4 (25%)	1/9 (11%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.654N	P=0.463N	P=0.673N	P=0.580N
POLY 1.5	P=0.658N	P=0.480N	P=0.692N	P=0.606N
POLY 6	P=0.645N	P=0.443N	P=0.643N	P=0.540N
COCH-ARM / FISHERS	P=0.666N	P=0.500N	P=0.697N	P=0.607N
MAX-ISO-POLY-3	P=0.471N	P=0.153N	P=0.398N	P=0.325N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Mammary Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	7/50 (14%)	13/50 (26%)	6/50 (12%)	8/50 (16%)
POLY-3 RATE (b)	7/43.72	13/43.63	6/43.79	8/41.85
POLY-3 PERCENT (g)	16%	29.8%	13.7%	19.1%
TERMINAL (d)	4/33 (12%)	7/29 (24%)	3/30 (10%)	4/25 (16%)
FIRST INCIDENCE	407	437	690	509

STATISTICAL TESTS

POLY 3	P=0.435N	P=0.098	P=0.499N	P=0.463
POLY 1.5	P=0.422N	P=0.100	P=0.500N	P=0.475
POLY 6	P=0.455N	P=0.095	P=0.501N	P=0.444
COCH-ARM / FISHERS	P=0.396N	P=0.105	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.368N	P=0.060	P=0.380N	P=0.355

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Mesentery
 Accessory Spleen

LESION RATES

OVERALL (a)	3/9 (33%)	0/9 (0%)	1/11 (9%)	1/7 (14%)
POLY-3 RATE (b)	3/8.56	0/7.62	1/10.38	1/6.52
POLY-3 PERCENT (g)	35.1%	0%	9.6%	15.4%
TERMINAL (d)	1/6 (17%)	0/5 (0%)	1/9 (11%)	0/3 (0%)
FIRST INCIDENCE	656	---	729 (T)	478

STATISTICAL TESTS

POLY 3	P=0.476N	P=0.110N	P=0.217N	P=0.398N
POLY 1.5	P=0.488N	P=0.101N	P=0.217N	P=0.394N
POLY 6	P=0.461N	P=0.125N	P=0.217N	P=0.406N
COCH-ARM / FISHERS	P=0.504N	P=0.103N	P=0.217N	P=0.392N
MAX-ISO-POLY-3	P=0.136N	P=0.036N*	P=0.098N	P=0.221N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Mesentery
 Hemorrhage**

LESION RATES

OVERALL (a)	0/9 (0%)	0/9 (0%)	2/11 (18%)	0/7 (0%)
POLY-3 RATE (b)	0/8.20	0/7.62	2/10.38	0/5.80
POLY-3 PERCENT (g)	0%	0%	19.3%	0%
TERMINAL (d)	0/6 (0%)	0/5 (0%)	2/9 (22%)	0/3 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.676	(e)	P=0.283	(e)
POLY 1.5	P=0.689	(e)	P=0.279	(e)
POLY 6	P=0.666	(e)	P=0.292	(e)
COCH-ARM / FISHERS	P=0.709	(e)	P=0.289	(e)
MAX-ISO-POLY-3	P=0.321	(e)	P=0.107	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Mesentery: Fat
 Necrosis**

LESION RATES

OVERALL (a)	4/9 (44%)	5/9 (56%)	7/11 (64%)	3/7 (43%)
POLY-3 RATE (b)	4/8.64	5/9.00	7/10.92	3/5.80
POLY-3 PERCENT (g)	46.3%	55.6%	64.1%	51.8%
TERMINAL (d)	3/6 (50%)	1/5 (20%)	6/9 (67%)	3/3 (100%)
FIRST INCIDENCE	600	506	563	729 (T)

STATISTICAL TESTS

POLY 3	P=0.544	P=0.534	P=0.375	P=0.624
POLY 1.5	P=0.604	P=0.518	P=0.361	P=0.657
POLY 6	P=0.478	P=0.561	P=0.397	P=0.588
COCH-ARM / FISHERS	P=0.532N	P=0.500	P=0.342	P=0.671N
MAX-ISO-POLY-3	P=0.536	P=0.357	P=0.236	P=0.430

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Nose
 Foreign Body

LESION RATES

OVERALL (a)	6/50 (12%)	5/50 (10%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	6/43.14	5/42.78	5/43.40	6/41.81
POLY-3 PERCENT (g)	13.9%	11.7%	11.5%	14.4%
TERMINAL (d)	4/33 (12%)	1/29 (3%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	600	530	729 (T)	590

STATISTICAL TESTS

POLY 3	P=0.492	P=0.506N	P=0.496N	P=0.599
POLY 1.5	P=0.499	P=0.503N	P=0.496N	P=0.606
POLY 6	P=0.483	P=0.513N	P=0.504N	P=0.588
COCH-ARM / FISHERS	P=0.514	P=0.500N	P=0.500N	P=0.620N
MAX-ISO-POLY-3	P=0.616	P=0.379N	P=0.369N	P=0.476

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	12/50 (24%)	4/50 (8%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	12/43.21	4/42.52	3/43.40	3/40.57
POLY-3 PERCENT (g)	27.8%	9.4%	6.9%	7.4%
TERMINAL (d)	9/33 (27%)	2/29 (7%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	593	506	729 (T)	635

STATISTICAL TESTS

POLY 3	P=0.028N*	P=0.026N*	P=0.009N**	P=0.014N*
POLY 1.5	P=0.027N*	P=0.026N*	P=0.010N**	P=0.012N*
POLY 6	P=0.030N*	P=0.027N*	P=0.009N**	P=0.016N*
COCH-ARM / FISHERS	P=0.028N*	P=0.027N*	P=0.011N*	P=0.011N*
MAX-ISO-POLY-3	P=0.005N**	P=0.013N*	P=0.004N**	P=0.008N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose: Respiratory Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	3/50 (6%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	5/42.70	3/41.78	3/43.50	3/40.98
POLY-3 PERCENT (g)	11.7%	7.2%	6.9%	7.3%
TERMINAL (d)	4/33 (12%)	2/29 (7%)	2/30 (7%)	0/25 (0%)
FIRST INCIDENCE	611	666	703	612

STATISTICAL TESTS

POLY 3	P=0.397N	P=0.368N	P=0.345N	P=0.378N
POLY 1.5	P=0.392N	P=0.362N	P=0.350N	P=0.371N
POLY 6	P=0.403N	P=0.378N	P=0.346N	P=0.392N
COCH-ARM / FISHERS	P=0.382N	P=0.357N	P=0.357N	P=0.357N
MAX-ISO-POLY-3	P=0.372N	P=0.242N	P=0.224N	P=0.253N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose: Respiratory Epithelium
 Metaplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/42.34	0/41.55	0/43.40	0/40.10
POLY-3 PERCENT (g)	4.7%	0%	0%	0%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	716	---	---	---

STATISTICAL TESTS

POLY 3	P=0.216N	P=0.241N	P=0.231N	P=0.249N
POLY 1.5	P=0.217N	P=0.239N	P=0.234N	P=0.244N
POLY 6	P=0.213N	P=0.245N	P=0.231N	P=0.257N
COCH-ARM / FISHERS	P=0.220N	P=0.247N	P=0.247N	P=0.247N
MAX-ISO-POLY-3	P=0.044N*	P=0.080N	P=0.076N	P=0.087N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas
 Atrophy**

LESION RATES

OVERALL (a)	19/50 (38%)	19/50 (38%)	25/49 (51%)	18/50 (36%)
POLY-3 RATE (b)	19/43.97	19/42.78	25/45.23	18/42.23
POLY-3 PERCENT (g)	43.2%	44.4%	55.3%	42.6%
TERMINAL (d)	14/33 (42%)	14/29 (48%)	18/30 (60%)	11/25 (44%)
FIRST INCIDENCE	575	642	534	450

STATISTICAL TESTS

POLY 3	P=0.505N	P=0.542	P=0.172	P=0.566N
POLY 1.5	P=0.480N	P=0.560	P=0.155	P=0.538N
POLY 6	P=0.546	P=0.512	P=0.187	P=0.561
COCH-ARM / FISHERS	P=0.445N	P=0.582N	P=0.135	P=0.500N
MAX-ISO-POLY-3	P=0.467	P=0.454	P=0.128	P=0.477N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas
 Cyst**

LESION RATES

OVERALL (a)	10/50 (20%)	12/50 (24%)	15/49 (31%)	14/50 (28%)
POLY-3 RATE (b)	10/43.92	12/43.34	15/43.95	14/41.74
POLY-3 PERCENT (g)	22.8%	27.7%	34.1%	33.5%
TERMINAL (d)	6/33 (18%)	7/29 (24%)	11/30 (37%)	10/25 (40%)
FIRST INCIDENCE	575	530	534	509

STATISTICAL TESTS

POLY 3	P=0.187	P=0.389	P=0.171	P=0.190
POLY 1.5	P=0.209	P=0.397	P=0.168	P=0.210
POLY 6	P=0.156	P=0.372	P=0.166	P=0.161
COCH-ARM / FISHERS	P=0.245	P=0.405	P=0.163	P=0.241
MAX-ISO-POLY-3	P=0.221	P=0.299	P=0.118	P=0.137

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas: Acinus
 Cytoplasmic Alteration**

LESION RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	0/49 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/43.09	3/43.49	0/42.86	1/41.08
POLY-3 PERCENT (g)	2.3%	6.9%	0%	2.4%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	422	437	---	208

STATISTICAL TESTS

POLY 3	P=0.431N	P=0.308	P=0.501N	P=0.750
POLY 1.5	P=0.427N	P=0.307	P=0.502N	P=0.755
POLY 6	P=0.439N	P=0.307	P=0.501N	P=0.742
COCH-ARM / FISHERS	P=0.421N	P=0.309	P=0.505N	P=0.753N
MAX-ISO-POLY-3	P=0.298N	P=0.157	P=0.160N	P=0.486

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas: Acinus
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	6/50 (12%)	0/50 (0%)	5/49 (10%)	1/50 (2%)
POLY-3 RATE (b)	6/43.77	0/41.55	5/42.86	1/40.10
POLY-3 PERCENT (g)	13.7%	0%	11.7%	2.5%
TERMINAL (d)	2/33 (6%)	0/29 (0%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	501	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.166N	P=0.018N*	P=0.515N	P=0.070N
POLY 1.5	P=0.161N	P=0.017N*	P=0.514N	P=0.064N
POLY 6	P=0.176N	P=0.020N*	P=0.524N	P=0.081N
COCH-ARM / FISHERS	P=0.155N	P=0.013N*	P=0.514N	P=0.056N
MAX-ISO-POLY-3	P=0.043N*	P=0.007N**	P=0.387N	P=0.036N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Angiectasis**

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	2/49 (4%)	5/50 (10%)
POLY-3 RATE (b)	2/42.75	4/41.90	2/43.25	5/40.10
POLY-3 PERCENT (g)	4.7%	9.6%	4.6%	12.5%
TERMINAL (d)	1/33 (3%)	3/29 (10%)	1/30 (3%)	5/25 (20%)
FIRST INCIDENCE	593	632	618	729 (T)

STATISTICAL TESTS

POLY 3	P=0.189	P=0.327	P=0.690N	P=0.189
POLY 1.5	P=0.199	P=0.332	P=0.694	P=0.200
POLY 6	P=0.174	P=0.319	P=0.688N	P=0.173
COCH-ARM / FISHERS	P=0.214	P=0.339	P=0.684	P=0.218
MAX-ISO-POLY-3	P=0.164	P=0.195	P=0.495N	P=0.107

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	7/50 (14%)	0/50 (0%)	6/49 (12%)	4/50 (8%)
POLY-3 RATE (b)	7/42.83	0/41.55	6/42.99	4/41.33
POLY-3 PERCENT (g)	16.4%	0%	14%	9.7%
TERMINAL (d)	6/33 (18%)	0/29 (0%)	5/30 (17%)	1/25 (4%)
FIRST INCIDENCE	563	---	696	450

STATISTICAL TESTS

POLY 3	P=0.559N	P=0.008N**	P=0.497N	P=0.280N
POLY 1.5	P=0.556N	P=0.008N**	P=0.504N	P=0.273N
POLY 6	P=0.564N	P=0.009N**	P=0.494N	P=0.295N
COCH-ARM / FISHERS	P=0.549N	P=0.006N**	P=0.516N	P=0.262N
MAX-ISO-POLY-3	P=0.165N	P=0.003N**	P=0.379N	P=0.187N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	14/50 (28%)	6/50 (12%)	8/49 (16%)	10/50 (20%)
POLY-3 RATE (b)	14/43.28	6/41.68	8/42.96	10/41.50
POLY-3 PERCENT (g)	32.4%	14.4%	18.6%	24.1%
TERMINAL (d)	10/33 (30%)	5/29 (17%)	7/30 (23%)	4/25 (16%)
FIRST INCIDENCE	593	696	703	572

STATISTICAL TESTS

POLY 3	P=0.492N	P=0.042N*	P=0.109N	P=0.272N
POLY 1.5	P=0.488N	P=0.040N*	P=0.114N	P=0.261N
POLY 6	P=0.497N	P=0.048N*	P=0.110N	P=0.293N
COCH-ARM / FISHERS	P=0.474N	P=0.039N*	P=0.124N	P=0.241N
MAX-ISO-POLY-3	P=0.117N	P=0.025N*	P=0.070N	P=0.203N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Intermedia
 Angiectasis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/42.86	0/40.10
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Intermedia
 Cyst**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	2/49 (4%)	5/50 (10%)
POLY-3 RATE (b)	3/42.75	2/41.84	2/42.86	5/40.92
POLY-3 PERCENT (g)	7%	4.8%	4.7%	12.2%
TERMINAL (d)	2/33 (6%)	1/29 (3%)	2/30 (7%)	1/25 (4%)
FIRST INCIDENCE	593	649	729 (T)	627

STATISTICAL TESTS

POLY 3	P=0.166	P=0.510N	P=0.499N	P=0.332
POLY 1.5	P=0.170	P=0.505N	P=0.503N	P=0.341
POLY 6	P=0.160	P=0.518N	P=0.499N	P=0.318
COCH-ARM / FISHERS	P=0.178	P=0.500N	P=0.510N	P=0.357
MAX-ISO-POLY-3	P=0.199	P=0.333N	P=0.323N	P=0.215

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Preputial Gland
 Cyst**

LESION RATES

OVERALL (a)	2/50 (4%)	1/50 (2%)	3/50 (6%)	0/50 (0%)
POLY-3 RATE (b)	2/42.77	1/41.79	3/43.40	0/40.10
POLY-3 PERCENT (g)	4.7%	2.4%	6.9%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	3/30 (10%)	0/25 (0%)
FIRST INCIDENCE	611	663	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.245N	P=0.508N	P=0.507	P=0.251N
POLY 1.5	P=0.237N	P=0.504N	P=0.505	P=0.246N
POLY 6	P=0.257N	P=0.515N	P=0.504	P=0.262N
COCH-ARM / FISHERS	P=0.226N	P=0.500N	P=0.500	P=0.247N
MAX-ISO-POLY-3	P=0.218N	P=0.289N	P=0.330	P=0.090N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Preputial Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/42.29	0/41.55	2/43.40	1/40.26
POLY-3 PERCENT (g)	4.7%	0%	4.6%	2.5%
TERMINAL (d)	2/33 (6%)	0/29 (0%)	2/30 (7%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	688

STATISTICAL TESTS

POLY 3	P=0.600N	P=0.241N	P=0.685N	P=0.517N
POLY 1.5	P=0.596N	P=0.239N	P=0.688N	P=0.510N
POLY 6	P=0.606N	P=0.244N	P=0.684N	P=0.528N
COCH-ARM / FISHERS	P=0.588N	P=0.247N	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.441N	P=0.079N	P=0.489N	P=0.299N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Preputial Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	19/50 (38%)	10/50 (20%)	14/50 (28%)	20/50 (40%)
POLY-3 RATE (b)	19/43.03	10/42.47	14/44.55	20/42.96
POLY-3 PERCENT (g)	44.2%	23.6%	31.4%	46.6%
TERMINAL (d)	16/33 (49%)	7/29 (24%)	8/30 (27%)	13/25 (52%)
FIRST INCIDENCE	600	530	618	478

STATISTICAL TESTS

POLY 3	P=0.141	P=0.033N*	P=0.153N	P=0.497
POLY 1.5	P=0.141	P=0.034N*	P=0.170N	P=0.495
POLY 6	P=0.138	P=0.034N*	P=0.138N	P=0.489
COCH-ARM / FISHERS	P=0.152	P=0.038N*	P=0.198N	P=0.500
MAX-ISO-POLY-3	P=0.148	P=0.020N*	P=0.109N	P=0.408

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Prostate
 Inflammation Chronic**

LESION RATES

OVERALL (a)	12/50 (24%)	15/50 (30%)	14/50 (28%)	10/50 (20%)
POLY-3 RATE (b)	12/44.46	15/43.39	14/45.02	10/41.19
POLY-3 PERCENT (g)	27%	34.6%	31.1%	24.3%
TERMINAL (d)	7/33 (21%)	8/29 (28%)	9/30 (30%)	5/25 (20%)
FIRST INCIDENCE	407	437	534	590

STATISTICAL TESTS

POLY 3	P=0.308N	P=0.294	P=0.423	P=0.484N
POLY 1.5	P=0.280N	P=0.308	P=0.417	P=0.454N
POLY 6	P=0.349N	P=0.276	P=0.423	P=0.528N
COCH-ARM / FISHERS	P=0.236N	P=0.326	P=0.410	P=0.405N
MAX-ISO-POLY-3	P=0.420N	P=0.223	P=0.335	P=0.389N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Prostate: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	4/50 (8%)	4/50 (8%)	5/50 (10%)	0/50 (0%)
POLY-3 RATE (b)	4/42.29	4/41.55	5/43.71	0/40.10
POLY-3 PERCENT (g)	9.5%	9.6%	11.4%	0%
TERMINAL (d)	4/33 (12%)	4/29 (14%)	4/30 (13%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	729 (T)	644	---

STATISTICAL TESTS

POLY 3	P=0.057N	P=0.634	P=0.521	P=0.067N
POLY 1.5	P=0.054N	P=0.639	P=0.512	P=0.064N
POLY 6	P=0.062N	P=0.625	P=0.526	P=0.071N
COCH-ARM / FISHERS	P=0.050N*	P=0.643N	P=0.500	P=0.059N
MAX-ISO-POLY-3	P=0.075N	P=0.489	P=0.383	P=0.025N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	4/50 (8%)	2/49 (4%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	4/43.31	2/41.33	4/43.74	6/40.10
POLY-3 PERCENT (g)	9.2%	4.8%	9.2%	15%
TERMINAL (d)	2/33 (6%)	2/29 (7%)	2/30 (7%)	6/25 (24%)
FIRST INCIDENCE	563	729 (T)	659	729 (T)

STATISTICAL TESTS

POLY 3	P=0.142	P=0.358N	P=0.638N	P=0.321
POLY 1.5	P=0.152	P=0.352N	P=0.640N	P=0.341
POLY 6	P=0.128	P=0.371N	P=0.641N	P=0.290
COCH-ARM / FISHERS	P=0.169	P=0.349N	P=0.643N	P=0.370
MAX-ISO-POLY-3	P=0.195	P=0.221N	P=0.493N	P=0.220

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Cyst Epithelial Inclusion**

LESION RATES

OVERALL (a)	1/50 (2%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	1/42.29	3/41.55	2/43.53	2/40.10
POLY-3 PERCENT (g)	2.4%	7.2%	4.6%	5%
TERMINAL (d)	1/33 (3%)	3/29 (10%)	1/30 (3%)	2/25 (8%)
FIRST INCIDENCE	729 (T)	729 (T)	696	729 (T)

STATISTICAL TESTS

POLY 3	P=0.548	P=0.298	P=0.510	P=0.481
POLY 1.5	P=0.558	P=0.302	P=0.506	P=0.489
POLY 6	P=0.531	P=0.292	P=0.512	P=0.469
COCH-ARM / FISHERS	P=0.574	P=0.309	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.412	P=0.151	P=0.292	P=0.270

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Edema

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.29	2/42.56	0/43.40	0/40.10
POLY-3 PERCENT (g)	0%	4.7%	0%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	355	---	---

STATISTICAL TESTS

POLY 3	P=0.375N	P=0.238	(e)	(e)
POLY 1.5	P=0.373N	P=0.239	(e)	(e)
POLY 6	P=0.380N	P=0.236	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.275N	P=0.077	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Hyperkeratosis**

LESION RATES

OVERALL (a)	4/50 (8%)	2/50 (4%)	4/50 (8%)	1/50 (2%)
POLY-3 RATE (b)	4/42.73	2/42.08	4/43.56	1/40.10
POLY-3 PERCENT (g)	9.4%	4.8%	9.2%	2.5%
TERMINAL (d)	3/33 (9%)	1/29 (3%)	3/30 (10%)	1/25 (4%)
FIRST INCIDENCE	600	565	688	729 (T)

STATISTICAL TESTS

POLY 3	P=0.217N	P=0.344N	P=0.633N	P=0.198N
POLY 1.5	P=0.208N	P=0.340N	P=0.637N	P=0.190N
POLY 6	P=0.230N	P=0.351N	P=0.634N	P=0.211N
COCH-ARM / FISHERS	P=0.195N	P=0.339N	P=0.643N	P=0.181N
MAX-ISO-POLY-3	P=0.182N	P=0.207N	P=0.488N	P=0.101N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Inflammation Chronic**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/42.29	0/41.55	2/43.40	0/40.10
POLY-3 PERCENT (g)	4.7%	0%	4.6%	0%
TERMINAL (d)	2/33 (6%)	0/29 (0%)	2/30 (7%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.293N	P=0.241N	P=0.685N	P=0.249N
POLY 1.5	P=0.289N	P=0.239N	P=0.688N	P=0.244N
POLY 6	P=0.299N	P=0.244N	P=0.684N	P=0.257N
COCH-ARM / FISHERS	P=0.282N	P=0.247N	P=0.691N	P=0.247N
MAX-ISO-POLY-3	P=0.140N	P=0.079N	P=0.489N	P=0.087N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin: Epidermis
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	0/50 (0%)	4/50 (8%)	0/50 (0%)
POLY-3 RATE (b)	5/42.73	0/41.55	4/43.56	0/40.10
POLY-3 PERCENT (g)	11.7%	0%	9.2%	0%
TERMINAL (d)	4/33 (12%)	0/29 (0%)	3/30 (10%)	0/25 (0%)
FIRST INCIDENCE	600	---	688	---

STATISTICAL TESTS

POLY 3	P=0.086N	P=0.032N*	P=0.488N	P=0.036N*
POLY 1.5	P=0.084N	P=0.032N*	P=0.492N	P=0.034N*
POLY 6	P=0.090N	P=0.034N*	P=0.488N	P=0.039N*
COCH-ARM / FISHERS	P=0.083N	P=0.028N*	P=0.500N	P=0.028N*
MAX-ISO-POLY-3	P=0.016N*	P=0.011N*	P=0.352N	P=0.014N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Spleen
 Accessory Spleen

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/42.11	1/41.55	0/42.86	0/40.10
POLY-3 PERCENT (g)	0%	2.4%	0%	0%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.577N	P=0.497	(e)	(e)
POLY 1.5	P=0.574N	P=0.500	(e)	(e)
POLY 6	P=0.580N	P=0.493	(e)	(e)
COCH-ARM / FISHERS	P=0.570N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.404N	P=0.160	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Fibrosis**

LESION RATES

OVERALL (a)	1/49 (2%)	2/50 (4%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/42.38	2/41.62	1/43.10	2/40.58
POLY-3 PERCENT (g)	2.4%	4.8%	2.3%	4.9%
TERMINAL (d)	0/33 (0%)	1/29 (3%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	656	711	663	656

STATISTICAL TESTS

POLY 3	P=0.457	P=0.494	P=0.757N	P=0.485
POLY 1.5	P=0.465	P=0.499	P=0.759N	P=0.493
POLY 6	P=0.446	P=0.485	P=0.756N	P=0.473
COCH-ARM / FISHERS	P=0.479	P=0.508	P=0.753N	P=0.508
MAX-ISO-POLY-3	P=0.438	P=0.278	P=0.494N	P=0.272

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	2/49 (4%)	8/50 (16%)	4/49 (8%)	11/50 (22%)
POLY-3 RATE (b)	2/43.36	8/43.43	4/43.80	11/44.63
POLY-3 PERCENT (g)	4.6%	18.4%	9.1%	24.7%
TERMINAL (d)	0/33 (0%)	2/29 (7%)	2/30 (7%)	1/25 (4%)
FIRST INCIDENCE	422	563	534	450

STATISTICAL TESTS

POLY 3	P=0.017*	P=0.044*	P=0.342	P=0.008**
POLY 1.5	P=0.017*	P=0.046*	P=0.339	P=0.008**
POLY 6	P=0.017*	P=0.044*	P=0.343	P=0.008**
COCH-ARM / FISHERS	P=0.018*	P=0.049*	P=0.339	P=0.008**
MAX-ISO-POLY-3	P=0.006**	P=0.021*	P=0.205	P=0.003**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hemorrhage**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	1/49 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/42.11	0/41.55	1/43.78	2/40.78
POLY-3 PERCENT (g)	0%	0%	2.3%	4.9%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	316	612

STATISTICAL TESTS

POLY 3	P=0.077	(e)	P=0.508	P=0.230
POLY 1.5	P=0.079	(e)	P=0.505	P=0.234
POLY 6	P=0.075	(e)	P=0.509	P=0.224
COCH-ARM / FISHERS	P=0.082	(e)	P=0.500	P=0.253
MAX-ISO-POLY-3	P=0.081	(e)	P=0.168	P=0.077

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	2/49 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/42.11	0/41.55	2/42.86	1/40.26
POLY-3 PERCENT (g)	0%	0%	4.7%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	2/30 (7%)	0/25 (0%)
FIRST INCIDENCE	---	---	729 (T)	688

STATISTICAL TESTS

POLY 3	P=0.311	(e)	P=0.241	P=0.491
POLY 1.5	P=0.320	(e)	P=0.239	P=0.496
POLY 6	P=0.299	(e)	P=0.242	P=0.484
COCH-ARM / FISHERS	P=0.335	(e)	P=0.247	P=0.505
MAX-ISO-POLY-3	P=0.188	(e)	P=0.080	P=0.160

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Infiltration Cellular Mixed Cell**

LESION RATES

OVERALL (a)	0/49 (0%)	3/50 (6%)	1/49 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/42.11	3/41.57	1/42.86	0/40.10
POLY-3 PERCENT (g)	0%	7.2%	2.3%	0%
TERMINAL (d)	0/33 (0%)	2/29 (7%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	---	723	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.301N	P=0.116	P=0.504	(e)
POLY 1.5	P=0.292N	P=0.119	P=0.502	(e)
POLY 6	P=0.313N	P=0.112	P=0.504	(e)
COCH-ARM / FISHERS	P=0.280N	P=0.125	P=0.500	(e)
MAX-ISO-POLY-3	P=0.246N	P=0.038*	P=0.163	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Necrosis**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	3/49 (6%)	1/50 (2%)
POLY-3 RATE (b)	0/42.11	0/41.55	3/43.11	1/40.51
POLY-3 PERCENT (g)	0%	0%	7%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	696	612

STATISTICAL TESTS

POLY 3	P=0.335	(e)	P=0.122	P=0.492
POLY 1.5	P=0.344	(e)	P=0.121	P=0.497
POLY 6	P=0.322	(e)	P=0.124	P=0.486
COCH-ARM / FISHERS	P=0.361	(e)	P=0.121	P=0.505
MAX-ISO-POLY-3	P=0.132	(e)	P=0.041*	P=0.160

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Stomach, Forestomach
 Edema

LESION RATES

OVERALL (a)	2/50 (4%)	5/50 (10%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	2/43.08	5/42.92	2/43.73	1/40.37
POLY-3 PERCENT (g)	4.6%	11.7%	4.6%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	571	563	644	656

STATISTICAL TESTS

POLY 3	P=0.207N	P=0.214	P=0.689N	P=0.523N
POLY 1.5	P=0.199N	P=0.215	P=0.690N	P=0.513N
POLY 6	P=0.221N	P=0.211	P=0.690N	P=0.537N
COCH-ARM / FISHERS	P=0.187N	P=0.218	P=0.691N	P=0.500N
MAX-ISO-POLY-3	P=0.236N	P=0.118	P=0.493N	P=0.305N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach
 Ulcer**

LESION RATES

OVERALL (a)	3/50 (6%)	8/50 (16%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	3/43.75	8/44.88	2/44.00	1/40.51
POLY-3 PERCENT (g)	6.9%	17.8%	4.6%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	501	355	644	612

STATISTICAL TESTS

POLY 3	P=0.069N	P=0.105	P=0.497N	P=0.333N
POLY 1.5	P=0.064N	P=0.104	P=0.498N	P=0.322N
POLY 6	P=0.077N	P=0.106	P=0.500N	P=0.350N
COCH-ARM / FISHERS	P=0.059N	P=0.100	P=0.500N	P=0.309N
MAX-ISO-POLY-3	P=0.085N	P=0.059	P=0.322N	P=0.182N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	5/50 (10%)	7/50 (14%)	3/50 (6%)	3/50 (6%)
POLY-3 RATE (b)	5/44.00	7/44.46	3/43.81	3/40.78
POLY-3 PERCENT (g)	11.4%	15.7%	6.9%	7.4%
TERMINAL (d)	1/33 (3%)	0/29 (0%)	0/30 (0%)	1/25 (4%)
FIRST INCIDENCE	501	530	644	612

STATISTICAL TESTS

POLY 3	P=0.214N	P=0.386	P=0.358N	P=0.398N
POLY 1.5	P=0.201N	P=0.383	P=0.357N	P=0.382N
POLY 6	P=0.235N	P=0.387	P=0.365N	P=0.424N
COCH-ARM / FISHERS	P=0.182N	P=0.380	P=0.357N	P=0.357N
MAX-ISO-POLY-3	P=0.286N	P=0.276	P=0.233N	P=0.273N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	3/50 (6%)	2/50 (4%)	3/50 (6%)	3/49 (6%)
POLY-3 RATE (b)	3/43.15	2/42.70	3/44.62	3/40.77
POLY-3 PERCENT (g)	7%	4.7%	6.7%	7.4%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	571	355	534	590

STATISTICAL TESTS

POLY 3	P=0.493	P=0.505N	P=0.647N	P=0.637
POLY 1.5	P=0.498	P=0.501N	P=0.652N	P=0.642
POLY 6	P=0.486	P=0.514N	P=0.646N	P=0.626
COCH-ARM / FISHERS	P=0.511	P=0.500N	P=0.661N	P=0.651
MAX-ISO-POLY-3	P=0.611	P=0.328N	P=0.482N	P=0.471

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular
 Ulcer**

LESION RATES

OVERALL (a)	0/50 (0%)	3/50 (6%)	2/50 (4%)	0/49 (0%)
POLY-3 RATE (b)	0/42.29	3/42.58	2/44.53	0/39.68
POLY-3 PERCENT (g)	0%	7%	4.5%	0%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	530	431	---

STATISTICAL TESTS

POLY 3	P=0.320N	P=0.119	P=0.249	(e)
POLY 1.5	P=0.314N	P=0.119	P=0.244	(e)
POLY 6	P=0.332N	P=0.119	P=0.252	(e)
COCH-ARM / FISHERS	P=0.305N	P=0.121	P=0.247	(e)
MAX-ISO-POLY-3	P=0.251	P=0.039*	P=0.087	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	3/50 (6%)	0/50 (0%)	1/50 (2%)	0/49 (0%)
POLY-3 RATE (b)	3/42.29	0/41.55	1/43.40	0/39.68
POLY-3 PERCENT (g)	7.1%	0%	2.3%	0%
TERMINAL (d)	3/33 (9%)	0/29 (0%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.151N	P=0.121N	P=0.296N	P=0.130N
POLY 1.5	P=0.150N	P=0.120N	P=0.299N	P=0.127N
POLY 6	P=0.151N	P=0.124N	P=0.294N	P=0.135N
COCH-ARM / FISHERS	P=0.151N	P=0.121N	P=0.309N	P=0.125N
MAX-ISO-POLY-3	P=0.033N*	P=0.040N*	P=0.150N	P=0.047N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Testes: Germinal Epithelium
 Atrophy

LESION RATES

OVERALL (a)	5/50 (10%)	8/50 (16%)	3/50 (6%)	8/50 (16%)
POLY-3 RATE (b)	5/42.36	8/43.00	3/44.86	8/42.16
POLY-3 PERCENT (g)	11.8%	18.6%	6.7%	19%
TERMINAL (d)	4/33 (12%)	4/29 (14%)	1/30 (3%)	4/25 (16%)
FIRST INCIDENCE	711	517	316	478

STATISTICAL TESTS

POLY 3	P=0.308	P=0.283	P=0.325N	P=0.270
POLY 1.5	P=0.312	P=0.281	P=0.336N	P=0.272
POLY 6	P=0.298	P=0.283	P=0.318N	P=0.260
COCH-ARM / FISHERS	P=0.318	P=0.277	P=0.357N	P=0.277
MAX-ISO-POLY-3	P=0.279	P=0.193	P=0.212N	P=0.181

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Testes: Interstitial Cell
 Hyperplasia

LESION RATES

OVERALL (a)	2/50 (4%)	6/50 (12%)	4/50 (8%)	3/50 (6%)
POLY-3 RATE (b)	2/43.16	6/42.56	4/44.98	3/41.58
POLY-3 PERCENT (g)	4.6%	14.1%	8.9%	7.2%
TERMINAL (d)	0/33 (0%)	2/29 (7%)	1/30 (3%)	1/25 (4%)
FIRST INCIDENCE	593	509	431	450

STATISTICAL TESTS

POLY 3	P=0.504N	P=0.127	P=0.356	P=0.483
POLY 1.5	P=0.494N	P=0.130	P=0.350	P=0.491
POLY 6	P=0.526N	P=0.121	P=0.358	P=0.467
COCH-ARM / FISHERS	P=0.481N	P=0.134	P=0.339	P=0.500
MAX-ISO-POLY-3	P=0.314	P=0.066	P=0.220	P=0.312

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus
 Atrophy**

LESION RATES

OVERALL (a)	0/48 (0%)	0/49 (0%)	0/49 (0%)	2/47 (4%)
POLY-3 RATE (b)	0/40.29	0/40.55	0/42.40	2/38.13
POLY-3 PERCENT (g)	0%	0%	0%	5.3%
TERMINAL (d)	0/31 (0%)	0/28 (0%)	0/29 (0%)	1/23 (4%)
FIRST INCIDENCE	---	---	---	208

STATISTICAL TESTS

POLY 3	P=0.037*	(e)	(e)	P=0.224
POLY 1.5	P=0.037*	(e)	(e)	P=0.229
POLY 6	P=0.035*	(e)	(e)	P=0.217
COCH-ARM / FISHERS	P=0.039*	(e)	(e)	P=0.242
MAX-ISO-POLY-3	P=0.032*	(e)	(e)	P=0.074

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus
 Cyst**

LESION RATES

OVERALL (a)	0/48 (0%)	2/49 (4%)	0/49 (0%)	0/47 (0%)
POLY-3 RATE (b)	0/40.29	2/40.57	0/42.40	0/37.15
POLY-3 PERCENT (g)	0%	4.9%	0%	0%
TERMINAL (d)	0/31 (0%)	1/28 (4%)	0/29 (0%)	0/23 (0%)
FIRST INCIDENCE	---	723	---	---

STATISTICAL TESTS

POLY 3	P=0.384N	P=0.238	(e)	(e)
POLY 1.5	P=0.380N	P=0.240	(e)	(e)
POLY 6	P=0.390N	P=0.235	(e)	(e)
COCH-ARM / FISHERS	P=0.376N	P=0.253	(e)	(e)
MAX-ISO-POLY-3	P=0.281N	P=0.077	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	8/50 (16%)	4/50 (8%)	4/50 (8%)	6/50 (12%)
POLY-3 RATE (b)	8/43.08	4/42.08	4/43.94	6/40.79
POLY-3 PERCENT (g)	18.6%	9.5%	9.1%	14.7%
TERMINAL (d)	6/33 (18%)	3/29 (10%)	3/30 (10%)	4/25 (16%)
FIRST INCIDENCE	571	565	563	572

STATISTICAL TESTS

POLY 3	P=0.550N	P=0.186N	P=0.165N	P=0.428N
POLY 1.5	P=0.541N	P=0.182N	P=0.170N	P=0.412N
POLY 6	P=0.565N	P=0.196N	P=0.165N	P=0.456N
COCH-ARM / FISHERS	P=0.523N	P=0.178N	P=0.178N	P=0.387N
MAX-ISO-POLY-3	P=0.259N	P=0.116N	P=0.101N	P=0.322N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicle
 Cyst**

LESION RATES

OVERALL (a)	3/50 (6%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	3/42.56	1/41.55	1/43.40	2/41.27
POLY-3 PERCENT (g)	7.1%	2.4%	2.3%	4.9%
TERMINAL (d)	2/33 (6%)	1/29 (3%)	1/30 (3%)	0/25 (0%)
FIRST INCIDENCE	656	729 (T)	729 (T)	450

STATISTICAL TESTS

POLY 3	P=0.586N	P=0.313N	P=0.298N	P=0.514N
POLY 1.5	P=0.585N	P=0.310N	P=0.301N	P=0.508N
POLY 6	P=0.589N	P=0.321N	P=0.299N	P=0.526N
COCH-ARM / FISHERS	P=0.583N	P=0.309N	P=0.309N	P=0.500N
MAX-ISO-POLY-3	P=0.311N	P=0.162N	P=0.151N	P=0.338N

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Males			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicular Cell
Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/42.29	0/41.55	0/43.40	1/40.87
POLY-3 PERCENT (g)	0%	0%	0%	2.5%
TERMINAL (d)	0/33 (0%)	0/29 (0%)	0/30 (0%)	0/25 (0%)
FIRST INCIDENCE	---	---	---	450

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STATISTICAL TESTS

POLY 3	P=0.207	(e)	(e)	P=0.493
POLY 1.5	P=0.208	(e)	(e)	P=0.496
POLY 6	P=0.204	(e)	(e)	P=0.488
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.126	(e)	(e)	P=0.158

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TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Accessory Adrenal Cortical Nodule**

LESION RATES

OVERALL (a)	3/50 (6%)	3/50 (6%)	9/50 (18%)	6/50 (12%)
POLY-3 RATE (b)	3/44.86	3/45.24	9/46.14	6/46.39
POLY-3 PERCENT (g)	6.7%	6.6%	19.5%	12.9%
TERMINAL (d)	3/30 (10%)	2/36 (6%)	8/42 (19%)	3/36 (8%)
FIRST INCIDENCE	729 (T)	647	666	687

STATISTICAL TESTS

POLY 3	P=0.201	P=0.659N	P=0.065	P=0.259
POLY 1.5	P=0.190	P=0.661	P=0.061	P=0.248
POLY 6	P=0.220	P=0.653N	P=0.074	P=0.275
COCH-ARM / FISHERS	P=0.184	P=0.661N	P=0.061	P=0.243
MAX-ISO-POLY-3	P=0.126	P=0.495N	P=0.036*	P=0.163

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Angiectasis**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	0/44.94	2/45.91	1/46.07
POLY-3 PERCENT (g)	0%	0%	4.4%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	2/42 (5%)	1/36 (3%)
FIRST INCIDENCE	---	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.343	(e)	P=0.242	P=0.505
POLY 1.5	P=0.336	(e)	P=0.238	P=0.502
POLY 6	P=0.353	(e)	P=0.250	P=0.510
COCH-ARM / FISHERS	P=0.331	(e)	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.184	(e)	P=0.081	P=0.165

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Degeneration Fatty**

LESION RATES

OVERALL (a)	9/50 (18%)	15/50 (30%)	11/50 (22%)	11/50 (22%)
POLY-3 RATE (b)	9/45.58	15/46.94	11/46.19	11/46.13
POLY-3 PERCENT (g)	19.7%	32%	23.8%	23.9%
TERMINAL (d)	6/30 (20%)	8/36 (22%)	10/42 (24%)	9/36 (25%)
FIRST INCIDENCE	575	568	652	716

STATISTICAL TESTS

POLY 3	P=0.506N	P=0.134	P=0.413	P=0.412
POLY 1.5	P=0.513N	P=0.124	P=0.399	P=0.402
POLY 6	P=0.497N	P=0.149	P=0.439	P=0.427
COCH-ARM / FISHERS	P=0.510N	P=0.121	P=0.402	P=0.402
MAX-ISO-POLY-3	P=0.368	P=0.092	P=0.320	P=0.319

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	5/50 (10%)	6/50 (12%)	4/50 (8%)	5/50 (10%)
POLY-3 RATE (b)	5/44.86	6/44.94	4/46.19	5/46.08
POLY-3 PERCENT (g)	11.2%	13.4%	8.7%	10.9%
TERMINAL (d)	5/30 (17%)	6/36 (17%)	3/42 (7%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	729 (T)	652	726

STATISTICAL TESTS

POLY 3	P=0.502N	P=0.501	P=0.482N	P=0.613N
POLY 1.5	P=0.512N	P=0.496	P=0.496N	P=0.624N
POLY 6	P=0.487N	P=0.507	P=0.458N	P=0.597N
COCH-ARM / FISHERS	P=0.519N	P=0.500	P=0.500N	P=0.630N
MAX-ISO-POLY-3	P=0.560N	P=0.374	P=0.348N	P=0.481N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Hypertrophy Focal**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	1/44.86	2/45.02	6/45.91	5/46.23
POLY-3 PERCENT (g)	2.2%	4.4%	13.1%	10.8%
TERMINAL (d)	1/30 (3%)	1/36 (3%)	6/42 (14%)	4/36 (11%)
FIRST INCIDENCE	729 (T)	709	729 (T)	687

STATISTICAL TESTS

POLY 3	P=0.094	P=0.501	P=0.059	P=0.108
POLY 1.5	P=0.089	P=0.498	P=0.057	P=0.104
POLY 6	P=0.103	P=0.505	P=0.065	P=0.115
COCH-ARM / FISHERS	P=0.086	P=0.500	P=0.056	P=0.102
MAX-ISO-POLY-3	P=0.068	P=0.282	P=0.027*	P=0.050*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.37	1/45.22	0/45.91	2/46.62
POLY-3 PERCENT (g)	2.2%	2.2%	0%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	653	---	575

STATISTICAL TESTS

POLY 3	P=0.345	P=0.760	P=0.498N	P=0.509
POLY 1.5	P=0.342	P=0.759	P=0.501N	P=0.503
POLY 6	P=0.351	P=0.760N	P=0.492N	P=0.519
COCH-ARM / FISHERS	P=0.338	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.294	P=0.498	P=0.159N	P=0.291

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Cortex
 Vacuolization Cytoplasmic Focal**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Adrenal Medulla
 Hyperplasia**

LESION RATES

OVERALL (a)	1/48 (2%)	2/50 (4%)	5/49 (10%)	7/50 (14%)
POLY-3 RATE (b)	1/43.73	2/44.94	5/45.14	7/46.61
POLY-3 PERCENT (g)	2.3%	4.5%	11.1%	15%
TERMINAL (d)	1/30 (3%)	2/36 (6%)	4/41 (10%)	6/36 (17%)
FIRST INCIDENCE	729 (T)	729 (T)	666	563

STATISTICAL TESTS

POLY 3	P=0.017*	P=0.510	P=0.108	P=0.037*
POLY 1.5	P=0.015*	P=0.509	P=0.105	P=0.035*
POLY 6	P=0.019*	P=0.512	P=0.116	P=0.040*
COCH-ARM / FISHERS	P=0.015*	P=0.515	P=0.107	P=0.034*
MAX-ISO-POLY-3	P=0.024*	P=0.289	P=0.050*	P=0.017*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Hyperplasia**

LESION RATES

OVERALL (a)	10/50 (20%)	3/50 (6%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	10/47.94	3/45.55	5/47.50	6/46.68
POLY-3 PERCENT (g)	20.9%	6.6%	10.5%	12.9%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	1/42 (2%)	3/36 (8%)
FIRST INCIDENCE	404	568	563	641

STATISTICAL TESTS

POLY 3	P=0.404N	P=0.043N*	P=0.134N	P=0.223N
POLY 1.5	P=0.408N	P=0.041N*	P=0.138N	P=0.221N
POLY 6	P=0.395N	P=0.047N*	P=0.127N	P=0.224N
COCH-ARM / FISHERS	P=0.411N	P=0.036N*	P=0.131N	P=0.207N
MAX-ISO-POLY-3	P=0.093N	P=0.025N*	P=0.083N	P=0.153N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	0/44.86	1/44.94	1/45.91	3/46.07
POLY-3 PERCENT (g)	0%	2.2%	2.2%	6.5%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	1/42 (2%)	3/36 (8%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.065	P=0.500	P=0.505	P=0.123
POLY 1.5	P=0.063	P=0.499	P=0.501	P=0.120
POLY 6	P=0.068	P=0.502	P=0.511	P=0.128
COCH-ARM / FISHERS	P=0.062	P=0.500	P=0.500	P=0.121
MAX-ISO-POLY-3	P=0.049*	P=0.159	P=0.164	P=0.042*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Bone Marrow
 Myelofibrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	5/50 (10%)
POLY-3 RATE (b)	1/44.99	1/45.28	0/45.91	5/47.38
POLY-3 PERCENT (g)	2.2%	2.2%	0%	10.6%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	696	635	---	563

STATISTICAL TESTS

POLY 3	P=0.014*	P=0.759N	P=0.496N	P=0.114
POLY 1.5	P=0.014*	P=0.760	P=0.500N	P=0.107
POLY 6	P=0.015*	P=0.757N	P=0.490N	P=0.124
COCH-ARM / FISHERS	P=0.014*	P=0.753N	P=0.500N	P=0.102
MAX-ISO-POLY-3	P=0.019*	P=0.497N	P=0.158N	P=0.055

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Compression**

LESION RATES

OVERALL (a)	9/50 (18%)	8/50 (16%)	3/50 (6%)	8/50 (16%)
POLY-3 RATE (b)	9/46.02	8/46.11	3/46.43	8/46.29
POLY-3 PERCENT (g)	19.6%	17.4%	6.5%	17.3%
TERMINAL (d)	5/30 (17%)	4/36 (11%)	2/42 (5%)	5/36 (14%)
FIRST INCIDENCE	537	589	569	687

STATISTICAL TESTS

POLY 3	P=0.497N	P=0.498N	P=0.057N	P=0.495N
POLY 1.5	P=0.500N	P=0.505N	P=0.060N	P=0.503N
POLY 6	P=0.490N	P=0.490N	P=0.052N	P=0.482N
COCH-ARM / FISHERS	P=0.500N	P=0.500N	P=0.061N	P=0.500N
MAX-ISO-POLY-3	P=0.246N	P=0.391N	P=0.030N*	P=0.388N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Hemorrhage**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.50	0/44.94	1/46.43	2/46.77
POLY-3 PERCENT (g)	4.4%	0%	2.2%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	537	---	569	575

STATISTICAL TESTS

POLY 3	P=0.425	P=0.240N	P=0.493N	P=0.684N
POLY 1.5	P=0.419	P=0.240N	P=0.499N	P=0.690N
POLY 6	P=0.434	P=0.239N	P=0.482N	P=0.674N
COCH-ARM / FISHERS	P=0.412	P=0.247N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.418N	P=0.079N	P=0.277N	P=0.488N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Brain
 Necrosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/45.37	0/44.94	0/45.91	1/46.58
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	---	---	575

STATISTICAL TESTS

POLY 3	P=0.551	P=0.502N	P=0.498N	P=0.755N
POLY 1.5	P=0.548	P=0.502N	P=0.501N	P=0.759N
POLY 6	P=0.555	P=0.502N	P=0.492N	P=0.749N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.406N	P=0.161N	P=0.159N	P=0.492N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral Gland
 Cyst**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/49 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.86	2/45.50	1/44.91	1/46.07
POLY-3 PERCENT (g)	2.2%	4.4%	2.2%	2.2%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	1/41 (2%)	1/36 (3%)
FIRST INCIDENCE	729 (T)	647	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.525N	P=0.505	P=0.760N	P=0.755N
POLY 1.5	P=0.530N	P=0.500	P=0.757	P=0.759N
POLY 6	P=0.518N	P=0.511	P=0.753N	P=0.749N
COCH-ARM / FISHERS	P=0.533N	P=0.500	P=0.747	P=0.753N
MAX-ISO-POLY-3	P=0.584N	P=0.286	P=0.499N	P=0.492N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	0/49 (0%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	2/45.58	0/44.91	0/46.07
POLY-3 PERCENT (g)	2.2%	4.4%	0%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/41 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	635	---	---

STATISTICAL TESTS

POLY 3	P=0.201N	P=0.506	P=0.500N	P=0.495N
POLY 1.5	P=0.203N	P=0.501	P=0.504N	P=0.498N
POLY 6	P=0.198N	P=0.512	P=0.493N	P=0.490N
COCH-ARM / FISHERS	P=0.204N	P=0.500	P=0.505N	P=0.500N
MAX-ISO-POLY-3	P=0.179N	P=0.287	P=0.160N	P=0.158N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	1/50 (2%)	5/50 (10%)	6/49 (12%)	0/50 (0%)
POLY-3 RATE (b)	1/44.86	5/45.32	6/44.91	0/46.07
POLY-3 PERCENT (g)	2.2%	11%	13.4%	0%
TERMINAL (d)	1/30 (3%)	3/36 (8%)	6/41 (15%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	647	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.132N	P=0.103	P=0.056	P=0.495N
POLY 1.5	P=0.139N	P=0.101	P=0.053	P=0.498N
POLY 6	P=0.122N	P=0.106	P=0.061	P=0.490N
COCH-ARM / FISHERS	P=0.148N	P=0.102	P=0.053	P=0.500N
MAX-ISO-POLY-3	P=0.071N	P=0.046*	P=0.024*	P=0.158N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Clitoral Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	4/50 (8%)	2/49 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/44.86	4/45.43	2/44.91	2/46.07
POLY-3 PERCENT (g)	0%	8.8%	4.5%	4.3%
TERMINAL (d)	0/30 (0%)	3/36 (8%)	2/41 (5%)	2/36 (6%)
FIRST INCIDENCE	---	585	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.545	P=0.062	P=0.237	P=0.243
POLY 1.5	P=0.535	P=0.060	P=0.233	P=0.239
POLY 6	P=0.559	P=0.063	P=0.244	P=0.249
COCH-ARM / FISHERS	P=0.530	P=0.059	P=0.242	P=0.247
MAX-ISO-POLY-3	P=0.144	P=0.020*	P=0.077	P=0.082

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Eye
 Cataract**

LESION RATES

OVERALL (a)	4/50 (8%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/45.04	2/44.94	1/45.91	2/46.07
POLY-3 PERCENT (g)	8.9%	4.5%	2.2%	4.3%
TERMINAL (d)	2/30 (7%)	2/36 (6%)	1/42 (2%)	2/36 (6%)
FIRST INCIDENCE	703	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.351N	P=0.338N	P=0.173N	P=0.327N
POLY 1.5	P=0.355N	P=0.341N	P=0.178N	P=0.334N
POLY 6	P=0.346N	P=0.336N	P=0.164N	P=0.317N
COCH-ARM / FISHERS	P=0.359N	P=0.339N	P=0.181N	P=0.339N
MAX-ISO-POLY-3	P=0.180N	P=0.201N	P=0.082N	P=0.195N

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Eye: Retina
Degeneration

LESION RATES

OVERALL (a)	4/50 (8%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/45.04	2/44.94	1/45.91	2/46.07
POLY-3 PERCENT (g)	8.9%	4.5%	2.2%	4.3%
TERMINAL (d)	2/30 (7%)	2/36 (6%)	1/42 (2%)	2/36 (6%)
FIRST INCIDENCE	703	729 (T)	729 (T)	729 (T)

.....
STATISTICAL TESTS

POLY 3	P=0.351N	P=0.338N	P=0.173N	P=0.327N
POLY 1.5	P=0.355N	P=0.341N	P=0.178N	P=0.334N
POLY 6	P=0.346N	P=0.336N	P=0.164N	P=0.317N
COCH-ARM / FISHERS	P=0.359N	P=0.339N	P=0.181N	P=0.339N
MAX-ISO-POLY-3	P=0.180N	P=0.201N	P=0.082N	P=0.195N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Harderian Gland
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/49 (0%)
POLY-3 RATE (b)	2/44.86	0/44.94	0/45.91	0/45.12
POLY-3 PERCENT (g)	4.5%	0%	0%	0%
TERMINAL (d)	2/30 (7%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.221N	P=0.237N	P=0.232N	P=0.236N
POLY 1.5	P=0.220N	P=0.238N	P=0.236N	P=0.240N
POLY 6	P=0.222N	P=0.235N	P=0.225N	P=0.230N
COCH-ARM / FISHERS	P=0.222N	P=0.247N	P=0.247N	P=0.253N
MAX-ISO-POLY-3	P=0.035N*	P=0.076N	P=0.076N	P=0.077N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Harderian Gland
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	2/45.65
POLY-3 PERCENT (g)	0%	0%	0%	4.4%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	---	---	---	568

STATISTICAL TESTS

POLY 3	P=0.041*	(e)	(e)	P=0.241
POLY 1.5	P=0.040*	(e)	(e)	P=0.236
POLY 6	P=0.042*	(e)	(e)	P=0.248
COCH-ARM / FISHERS	P=0.040*	(e)	(e)	P=0.242
MAX-ISO-POLY-3	P=0.038*	(e)	(e)	P=0.081

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Heart
 Cardiomyopathy**

LESION RATES

OVERALL (a)	24/50 (48%)	24/50 (48%)	21/50 (42%)	15/50 (30%)
POLY-3 RATE (b)	24/46.59	24/46.04	21/45.91	15/46.34
POLY-3 PERCENT (g)	51.5%	52.1%	45.7%	32.4%
TERMINAL (d)	17/30 (57%)	19/36 (53%)	21/42 (50%)	11/36 (31%)
FIRST INCIDENCE	575	627	729 (T)	687

STATISTICAL TESTS

POLY 3	P=0.019N*	P=0.560	P=0.363N	P=0.045N*
POLY 1.5	P=0.022N*	P=0.556	P=0.369N	P=0.049N*
POLY 6	P=0.017N*	P=0.561	P=0.350N	P=0.041N*
COCH-ARM / FISHERS	P=0.024N*	P=0.579N	P=0.344N	P=0.050N*
MAX-ISO-POLY-3	P=0.031N*	P=0.475	P=0.290N	P=0.028N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Intestine Large, Cecum
 Edema

LESION RATES

OVERALL (a)	1/48 (2%)	0/50 (0%)	0/50 (0%)	2/49 (4%)
POLY-3 RATE (b)	1/43.04	0/44.94	0/45.91	2/45.80
POLY-3 PERCENT (g)	2.3%	0%	0%	4.4%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	0/42 (0%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	---	563

STATISTICAL TESTS

POLY 3	P=0.201	P=0.491N	P=0.487N	P=0.522
POLY 1.5	P=0.198	P=0.493N	P=0.491N	P=0.513
POLY 6	P=0.205	P=0.490N	P=0.481N	P=0.533
COCH-ARM / FISHERS	P=0.195	P=0.490N	P=0.490N	P=0.508
MAX-ISO-POLY-3	P=0.156	P=0.156N	P=0.156N	P=0.303

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Cyst**

LESION RATES

OVERALL (a)	1/49 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/43.89	0/44.94	1/45.91	0/46.07
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	1/42 (2%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.449N	P=0.495N	P=0.751N	P=0.490N
POLY 1.5	P=0.451N	P=0.497N	P=0.755N	P=0.494N
POLY 6	P=0.445N	P=0.493N	P=0.743N	P=0.485N
COCH-ARM / FISHERS	P=0.453N	P=0.495N	P=0.747N	P=0.495N
MAX-ISO-POLY-3	P=0.254N	P=0.157N	P=0.487N	P=0.157N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Infarct**

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.89	1/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	0%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.569N	P=0.505	(e)	(e)
POLY 1.5	P=0.570N	P=0.503	(e)	(e)
POLY 6	P=0.567N	P=0.507	(e)	(e)
COCH-ARM / FISHERS	P=0.570N	P=0.505	(e)	(e)
MAX-ISO-POLY-3	P=0.390N	P=0.163	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney
 Nephropathy**

LESION RATES

OVERALL (a)	36/49 (73%)	24/50 (48%)	33/50 (66%)	45/50 (90%)
POLY-3 RATE (b)	36/46.26	24/46.19	33/47.16	45/48.99
POLY-3 PERCENT (g)	77.8%	52%	70%	91.9%
TERMINAL (d)	26/30 (87%)	19/36 (53%)	31/42 (74%)	33/36 (92%)
FIRST INCIDENCE	575	589	474	563

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.006N**	P=0.259N	P=0.043*
POLY 1.5	P<0.001**	P=0.007N**	P=0.284N	P=0.028*
POLY 6	P<0.001**	P=0.005N**	P=0.232N	P=0.077
COCH-ARM / FISHERS	P<0.001**	P=0.008N**	P=0.278N	P=0.030*
MAX-ISO-POLY-3	P<0.001**	P=0.003N**	P=0.188N	P=0.024*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Accumulation, Hyaline Droplet**

LESION RATES

OVERALL (a)	2/49 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	2/43.89	0/44.94	1/45.91	1/46.07
POLY-3 PERCENT (g)	4.6%	0%	2.2%	2.2%
TERMINAL (d)	2/30 (7%)	0/36 (0%)	1/42 (2%)	1/36 (3%)
FIRST INCIDENCE	729 (T)	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.594N	P=0.232N	P=0.484N	P=0.483N
POLY 1.5	P=0.596N	P=0.234N	P=0.491N	P=0.490N
POLY 6	P=0.591N	P=0.229N	P=0.473N	P=0.474N
COCH-ARM / FISHERS	P=0.599N	P=0.242N	P=0.492N	P=0.492N
MAX-ISO-POLY-3	P=0.267N	P=0.075N	P=0.271N	P=0.270N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Necrosis**

LESION RATES

OVERALL (a)	1/49 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.40	0/44.94	0/45.91	1/46.26
POLY-3 PERCENT (g)	2.3%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	---	---	678

STATISTICAL TESTS

POLY 3	P=0.552	P=0.498N	P=0.493N	P=0.751N
POLY 1.5	P=0.550	P=0.498N	P=0.496N	P=0.755N
POLY 6	P=0.556	P=0.497N	P=0.488N	P=0.746N
COCH-ARM / FISHERS	P=0.547	P=0.495N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.401N	P=0.157N	P=0.157N	P=0.488N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Renal Tubule
 Pigmentation**

LESION RATES

OVERALL (a)	1/49 (2%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	1/44.40	1/45.22	1/46.19	2/46.66
POLY-3 PERCENT (g)	2.3%	2.2%	2.2%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	653	652	563

STATISTICAL TESTS

POLY 3	P=0.374	P=0.757N	P=0.752N	P=0.517
POLY 1.5	P=0.368	P=0.758N	P=0.756N	P=0.511
POLY 6	P=0.383	P=0.755N	P=0.745N	P=0.527
COCH-ARM / FISHERS	P=0.362	P=0.747N	P=0.747N	P=0.508
MAX-ISO-POLY-3	P=0.446	P=0.494N	P=0.488N	P=0.298

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Kidney: Transitional Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	2/49 (4%)	0/50 (0%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	2/44.44	0/44.94	2/45.91	0/46.07
POLY-3 PERCENT (g)	4.5%	0%	4.4%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	2/42 (5%)	0/36 (0%)
FIRST INCIDENCE	575	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.272N	P=0.235N	P=0.682N	P=0.229N
POLY 1.5	P=0.275N	P=0.235N	P=0.687N	P=0.232N
POLY 6	P=0.267N	P=0.234N	P=0.673N	P=0.225N
COCH-ARM / FISHERS	P=0.279N	P=0.242N	P=0.684N	P=0.242N
MAX-ISO-POLY-3	P=0.120N	P=0.075N	P=0.486N	P=0.075N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver
 Angiectasis**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	1/44.94	2/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	4.4%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	2/42 (5%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.520N	P=0.500	P=0.242	(e)
POLY 1.5	P=0.526N	P=0.499	P=0.238	(e)
POLY 6	P=0.510N	P=0.502	P=0.250	(e)
COCH-ARM / FISHERS	P=0.530N	P=0.500	P=0.247	(e)
MAX-ISO-POLY-3	P=0.337N	P=0.159	P=0.081	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Basophilic Focus

LESION RATES

OVERALL (a)	44/50 (88%)	44/50 (88%)	46/50 (92%)	27/50 (54%)
POLY-3 RATE (b)	44/48.73	44/47.50	46/47.74	27/46.84
POLY-3 PERCENT (g)	90.3%	92.6%	96.4%	57.6%
TERMINAL (d)	29/30 (97%)	36/36 (100%)	41/42 (98%)	25/36 (69%)
FIRST INCIDENCE	404	568	563	563

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.480	P=0.194	P<0.001N**
POLY 1.5	P<0.001N**	P=0.504	P=0.209	P<0.001N**
POLY 6	P<0.001N**	P=0.427	P=0.210	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.620N	P=0.370	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.326	P=0.097	P<0.001N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Clear Cell Focus

LESION RATES

OVERALL (a)	4/50 (8%)	5/50 (10%)	10/50 (20%)	2/50 (4%)
POLY-3 RATE (b)	4/44.86	5/44.94	10/45.91	2/46.07
POLY-3 PERCENT (g)	8.9%	11.1%	21.8%	4.3%
TERMINAL (d)	4/30 (13%)	5/36 (14%)	10/42 (24%)	2/36 (6%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.204N	P=0.501	P=0.078	P=0.325N
POLY 1.5	P=0.216N	P=0.497	P=0.073	P=0.333N
POLY 6	P=0.187N	P=0.506	P=0.087	P=0.313N
COCH-ARM / FISHERS	P=0.228N	P=0.500	P=0.074	P=0.339N
MAX-ISO-POLY-3	P=0.120N	P=0.364	P=0.045*	P=0.194N

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
Degeneration Cystic

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver
 Eosinophilic Focus**

LESION RATES

OVERALL (a)	2/50 (4%)	24/50 (48%)	29/50 (58%)	22/50 (44%)
POLY-3 RATE (b)	2/45.02	24/45.88	29/46.92	22/46.46
POLY-3 PERCENT (g)	4.4%	52.3%	61.8%	47.4%
TERMINAL (d)	1/30 (3%)	20/36 (56%)	26/42 (62%)	19/36 (53%)
FIRST INCIDENCE	689	568	569	666

STATISTICAL TESTS

POLY 3	P=0.004**	P<0.001**	P<0.001**	P<0.001**
POLY 1.5	P=0.004**	P<0.001**	P<0.001**	P<0.001**
POLY 6	P=0.006**	P<0.001**	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P=0.007**	P<0.001**	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P<0.001**	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hemorrhage

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	1/44.94	1/46.44	1/46.07
POLY-3 PERCENT (g)	0%	2.2%	2.2%	2.2%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	---	729 (T)	565	729 (T)

STATISTICAL TESTS

POLY 3	P=0.481	P=0.500	P=0.507	P=0.505
POLY 1.5	P=0.474	P=0.499	P=0.502	P=0.502
POLY 6	P=0.490	P=0.502	P=0.515	P=0.510
COCH-ARM / FISHERS	P=0.470	P=0.500	P=0.500	P=0.500
MAX-ISO-POLY-3	P=0.344	P=0.159	P=0.167	P=0.165

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Hepatodiaphragmatic Nodule

LESION RATES

OVERALL (a)	7/50 (14%)	17/50 (34%)	8/50 (16%)	9/50 (18%)
POLY-3 RATE (b)	7/45.86	17/46.11	8/46.67	9/46.84
POLY-3 PERCENT (g)	15.3%	36.9%	17.1%	19.2%
TERMINAL (d)	4/30 (13%)	14/36 (39%)	6/42 (14%)	7/36 (19%)
FIRST INCIDENCE	575	568	569	563

STATISTICAL TESTS

POLY 3	P=0.312N	P=0.015*	P=0.515	P=0.410
POLY 1.5	P=0.326N	P=0.014*	P=0.500	P=0.398
POLY 6	P=0.291N	P=0.015*	P=0.539	P=0.428
COCH-ARM / FISHERS	P=0.337N	P=0.017*	P=0.500	P=0.393
MAX-ISO-POLY-3	P=0.235	P=0.008**	P=0.402	P=0.310

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Infiltration Cellular Mixed Cell

LESION RATES

OVERALL (a)	7/50 (14%)	7/50 (14%)	9/50 (18%)	11/50 (22%)
POLY-3 RATE (b)	7/46.45	7/46.15	9/45.91	11/46.44
POLY-3 PERCENT (g)	15.1%	15.2%	19.6%	23.7%
TERMINAL (d)	4/30 (13%)	4/36 (11%)	9/42 (21%)	7/36 (19%)
FIRST INCIDENCE	404	568	729 (T)	687

STATISTICAL TESTS

POLY 3	P=0.144	P=0.608	P=0.382	P=0.215
POLY 1.5	P=0.141	P=0.604	P=0.378	P=0.211
POLY 6	P=0.151	P=0.611N	P=0.396	P=0.226
COCH-ARM / FISHERS	P=0.144	P=0.613N	P=0.393	P=0.218
MAX-ISO-POLY-3	P=0.230	P=0.494	P=0.285	P=0.146

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Mixed Cell Focus

LESION RATES

OVERALL (a)	6/50 (12%)	5/50 (10%)	13/50 (26%)	9/50 (18%)
POLY-3 RATE (b)	6/44.86	5/44.94	13/45.91	9/46.07
POLY-3 PERCENT (g)	13.4%	11.1%	28.3%	19.5%
TERMINAL (d)	6/30 (20%)	5/36 (14%)	13/42 (31%)	9/36 (25%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.212	P=0.499N	P=0.066	P=0.306
POLY 1.5	P=0.200	P=0.504N	P=0.061	P=0.294
POLY 6	P=0.231	P=0.493N	P=0.075	P=0.324
COCH-ARM / FISHERS	P=0.194	P=0.500N	P=0.062	P=0.288
MAX-ISO-POLY-3	P=0.120	P=0.372N	P=0.040*	P=0.218

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver
 Necrosis Focal

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.94	0/44.94	0/45.91	1/46.12
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	709	---	---	716

STATISTICAL TESTS

POLY 3	P=0.549	P=0.500N	P=0.496N	P=0.755N
POLY 1.5	P=0.547	P=0.501N	P=0.499N	P=0.759N
POLY 6	P=0.552	P=0.499N	P=0.490N	P=0.749N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.158N	P=0.492N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Bile Duct
 Hyperplasia

LESION RATES

OVERALL (a)	2/50 (4%)	4/50 (8%)	9/50 (18%)	3/50 (6%)
POLY-3 RATE (b)	2/44.99	4/45.82	9/46.44	3/46.61
POLY-3 PERCENT (g)	4.5%	8.7%	19.4%	6.4%
TERMINAL (d)	1/30 (3%)	1/36 (3%)	8/42 (19%)	2/36 (6%)
FIRST INCIDENCE	696	647	565	563

STATISTICAL TESTS

POLY 3	P=0.570N	P=0.346	P=0.028*	P=0.516
POLY 1.5	P=0.580	P=0.339	P=0.026*	P=0.506
POLY 6	P=0.549N	P=0.355	P=0.033*	P=0.529
COCH-ARM / FISHERS	P=0.566	P=0.339	P=0.026*	P=0.500
MAX-ISO-POLY-3	P=0.143	P=0.209	P=0.014*	P=0.340

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Centrilobular
 Necrosis

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/45.37	0/44.94	1/46.19	0/46.07
POLY-3 PERCENT (g)	2.2%	0%	2.2%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	---	652	---

STATISTICAL TESTS

POLY 3	P=0.451N	P=0.502N	P=0.757N	P=0.497N
POLY 1.5	P=0.454N	P=0.502N	P=0.760N	P=0.500N
POLY 6	P=0.448N	P=0.502N	P=0.750N	P=0.493N
COCH-ARM / FISHERS	P=0.456N	P=0.500N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.257N	P=0.161N	P=0.494N	P=0.159N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver: Hepatocyte
 Degeneration**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	12/50 (24%)	24/50 (48%)
POLY-3 RATE (b)	1/44.86	2/44.94	12/45.91	24/46.59
POLY-3 PERCENT (g)	2.2%	4.5%	26.1%	51.5%
TERMINAL (d)	1/30 (3%)	2/36 (6%)	12/42 (29%)	23/36 (64%)
FIRST INCIDENCE	729 (T)	729 (T)	729 (T)	568

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.501	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.498	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.504	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.500	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.281	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Hepatocyte
 Hypertrophy

LESION RATES

OVERALL (a)	2/50 (4%)	10/50 (20%)	27/50 (54%)	38/50 (76%)
POLY-3 RATE (b)	2/44.90	10/45.86	27/46.45	38/47.10
POLY-3 PERCENT (g)	4.5%	21.8%	58.1%	80.7%
TERMINAL (d)	1/30 (3%)	7/36 (19%)	26/42 (62%)	34/36 (94%)
FIRST INCIDENCE	719	589	563	568

STATISTICAL TESTS

POLY 3	P<0.001**	P=0.014*	P<0.001**	P<0.001**
POLY 1.5	P<0.001**	P=0.014*	P<0.001**	P<0.001**
POLY 6	P<0.001**	P=0.016*	P<0.001**	P<0.001**
COCH-ARM / FISHERS	P<0.001**	P=0.014*	P<0.001**	P<0.001**
MAX-ISO-POLY-3	P<0.001**	P=0.007**	P<0.001**	P<0.001**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Liver: Hepatocyte
 Vacuolization Cytoplasmic

LESION RATES

OVERALL (a)	4/50 (8%)	4/50 (8%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	4/46.15	4/45.78	1/45.91	3/46.68
POLY-3 PERCENT (g)	8.7%	8.7%	2.2%	6.4%
TERMINAL (d)	1/30 (3%)	1/36 (3%)	1/42 (2%)	0/36 (0%)
FIRST INCIDENCE	575	647	729 (T)	575

STATISTICAL TESTS

POLY 3	P=0.408N	P=0.639	P=0.180N	P=0.494N
POLY 1.5	P=0.412N	P=0.637	P=0.183N	P=0.500N
POLY 6	P=0.403N	P=0.642	P=0.176N	P=0.485N
COCH-ARM / FISHERS	P=0.415N	P=0.643N	P=0.181N	P=0.500N
MAX-ISO-POLY-3	P=0.321N	P=0.495	P=0.085N	P=0.343N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Liver: Kupffer Cell
 Pigmentation**

LESION RATES

OVERALL (a)	1/50 (2%)	2/50 (4%)	1/50 (2%)	3/50 (6%)
POLY-3 RATE (b)	1/44.99	2/45.57	1/46.63	3/47.09
POLY-3 PERCENT (g)	2.2%	4.4%	2.1%	6.4%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	696	639	474	575

STATISTICAL TESTS

POLY 3	P=0.261	P=0.504	P=0.753N	P=0.322
POLY 1.5	P=0.253	P=0.500	P=0.758N	P=0.312
POLY 6	P=0.272	P=0.510	P=0.745N	P=0.336
COCH-ARM / FISHERS	P=0.246	P=0.500	P=0.753N	P=0.309
MAX-ISO-POLY-3	P=0.253	P=0.286	P=0.489N	P=0.172

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Hemorrhage**

LESION RATES

OVERALL (a)	6/50 (12%)	0/50 (0%)	2/50 (4%)	10/50 (20%)
POLY-3 RATE (b)	6/45.97	0/44.94	2/45.91	10/46.26
POLY-3 PERCENT (g)	13.1%	0%	4.4%	21.6%
TERMINAL (d)	4/30 (13%)	0/36 (0%)	2/42 (5%)	9/36 (25%)
FIRST INCIDENCE	537	---	729 (T)	678

STATISTICAL TESTS

POLY 3	P=0.007**	P=0.016N*	P=0.133N	P=0.209
POLY 1.5	P=0.007**	P=0.016N*	P=0.137N	P=0.204
POLY 6	P=0.008**	P=0.016N*	P=0.126N	P=0.218
COCH-ARM / FISHERS	P=0.008**	P=0.013N*	P=0.134N	P=0.207
MAX-ISO-POLY-3	P=0.007**	P=0.005N**	P=0.069N	P=0.139

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Infiltration Cellular Histiocyte**

LESION RATES

OVERALL (a)	39/50 (78%)	34/50 (68%)	37/50 (74%)	39/50 (78%)
POLY-3 RATE (b)	39/46.91	34/46.99	37/48.23	39/47.32
POLY-3 PERCENT (g)	83.1%	72.4%	76.7%	82.4%
TERMINAL (d)	27/30 (90%)	27/36 (75%)	32/42 (76%)	32/36 (89%)
FIRST INCIDENCE	537	568	474	641

STATISTICAL TESTS

POLY 3	P=0.355	P=0.144N	P=0.293N	P=0.576N
POLY 1.5	P=0.335	P=0.172N	P=0.368N	P=0.602
POLY 6	P=0.400	P=0.118N	P=0.207N	P=0.514N
COCH-ARM / FISHERS	P=0.345	P=0.184N	P=0.408N	P=0.595N
MAX-ISO-POLY-3	P=0.379N	P=0.093N	P=0.213N	P=0.460N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Inflammation Chronic**

LESION RATES

OVERALL (a)	18/50 (36%)	21/50 (42%)	19/50 (38%)	14/50 (28%)
POLY-3 RATE (b)	18/45.63	21/45.03	19/47.41	14/46.07
POLY-3 PERCENT (g)	39.5%	46.6%	40.1%	30.4%
TERMINAL (d)	12/30 (40%)	19/36 (53%)	16/42 (38%)	14/36 (39%)
FIRST INCIDENCE	663	709	474	729 (T)

STATISTICAL TESTS

POLY 3	P=0.109N	P=0.314	P=0.560	P=0.243N
POLY 1.5	P=0.120N	P=0.318	P=0.522	P=0.257N
POLY 6	P=0.097N	P=0.302	P=0.560N	P=0.229N
COCH-ARM / FISHERS	P=0.129N	P=0.341	P=0.500	P=0.260N
MAX-ISO-POLY-3	P=0.173N	P=0.244	P=0.475	P=0.181N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung
 Metaplasia Osseous**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	0/44.86	2/44.94	2/45.91	2/46.07
POLY-3 PERCENT (g)	0%	4.5%	4.4%	4.3%
TERMINAL (d)	0/30 (0%)	2/36 (6%)	2/42 (5%)	2/36 (6%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.339	P=0.237	P=0.242	P=0.243
POLY 1.5	P=0.331	P=0.236	P=0.238	P=0.239
POLY 6	P=0.350	P=0.239	P=0.250	P=0.249
COCH-ARM / FISHERS	P=0.326	P=0.247	P=0.247	P=0.247
MAX-ISO-POLY-3	P=0.203	P=0.076	P=0.081	P=0.082

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lung: Alveolar Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	7/50 (14%)	7/50 (14%)	5/50 (10%)	6/50 (12%)
POLY-3 RATE (b)	7/45.46	7/45.78	5/45.91	6/46.75
POLY-3 PERCENT (g)	15.4%	15.3%	10.9%	12.8%
TERMINAL (d)	6/30 (20%)	5/36 (14%)	5/42 (12%)	4/36 (11%)
FIRST INCIDENCE	537	589	729 (T)	575

STATISTICAL TESTS

POLY 3	P=0.417N	P=0.608N	P=0.372N	P=0.478N
POLY 1.5	P=0.428N	P=0.611	P=0.382N	P=0.493N
POLY 6	P=0.399N	P=0.598N	P=0.353N	P=0.456N
COCH-ARM / FISHERS	P=0.436N	P=0.613N	P=0.380N	P=0.500N
MAX-ISO-POLY-3	P=0.500N	P=0.494N	P=0.264N	P=0.363N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric
 Ectasia**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/43.89	0/44.94	0/45.91	1/45.39
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	---	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.214	(e)	(e)	P=0.507
POLY 1.5	P=0.211	(e)	(e)	P=0.502
POLY 6	P=0.218	(e)	(e)	P=0.513
COCH-ARM / FISHERS	P=0.209	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.136	(e)	(e)	P=0.167

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node, Mesenteric Hemorrhage

LESION RATES

OVERALL (a)	3/49 (6%)	1/50 (2%)	3/50 (6%)	3/49 (6%)
POLY-3 RATE (b)	3/43.98	1/45.94	3/45.91	3/46.38
POLY-3 PERCENT (g)	6.8%	2.2%	6.5%	6.5%
TERMINAL (d)	1/30 (3%)	0/36 (0%)	3/42 (7%)	2/36 (6%)
FIRST INCIDENCE	716	59	729 (T)	122

STATISTICAL TESTS

POLY 3	P=0.457	P=0.290N	P=0.643N	P=0.638N
POLY 1.5	P=0.448	P=0.293N	P=0.651N	P=0.648N
POLY 6	P=0.471	P=0.286N	P=0.628N	P=0.624N
COCH-ARM / FISHERS	P=0.435	P=0.301N	P=0.651N	P=0.661N
MAX-ISO-POLY-3	P=0.537	P=0.147N	P=0.478N	P=0.473N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node, Mesenteric
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	15/49 (31%)	8/50 (16%)	10/50 (20%)	9/49 (18%)
POLY-3 RATE (b)	15/45.75	8/45.51	10/46.72	9/45.50
POLY-3 PERCENT (g)	32.8%	17.6%	21.4%	19.8%
TERMINAL (d)	9/30 (30%)	6/36 (17%)	8/42 (19%)	8/36 (22%)
FIRST INCIDENCE	404	585	569	701

STATISTICAL TESTS

POLY 3	P=0.223N	P=0.074N	P=0.158N	P=0.119N
POLY 1.5	P=0.231N	P=0.074N	P=0.168N	P=0.124N
POLY 6	P=0.210N	P=0.072N	P=0.140N	P=0.109N
COCH-ARM / FISHERS	P=0.234N	P=0.069N	P=0.163N	P=0.120N
MAX-ISO-POLY-3	P=0.106N	P=0.046N*	P=0.109N	P=0.078N

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Mediastinal
Ectasia

LESION RATES

OVERALL (a)	0/9 (0%)	0/7 (0%)	0/7 (0%)	0/8 (0%)
POLY-3 RATE (b)	0/7.68	0/4.38	0/5.65	0/7.40
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/3 (0%)	0/1 (0%)	0/4 (0%)	0/3 (0%)
FIRST INCIDENCE	---	---	---	---

.....
STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

.....

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Mediastinal Hemorrhage

LESION RATES

OVERALL (a)	5/9 (56%)	2/7 (29%)	4/7 (57%)	1/8 (13%)
POLY-3 RATE (b)	5/8.28	2/4.46	4/6.46	1/7.40
POLY-3 PERCENT (g)	60.4%	44.8%	61.9%	13.5%
TERMINAL (d)	2/3 (67%)	1/1 (100%)	2/4 (50%)	1/3 (33%)
FIRST INCIDENCE	575	709	569	729 (T)

STATISTICAL TESTS

POLY 3	P=0.040N*	P=0.522N	P=0.680	P=0.066N
POLY 1.5	P=0.053N	P=0.448N	P=0.669	P=0.071N
POLY 6	P=0.028N*	P=0.651N	P=0.707	P=0.060N
COCH-ARM / FISHERS	P=0.096N	P=0.286N	P=0.671	P=0.088N
MAX-ISO-POLY-3	P=0.037N*	P=0.335N	P=0.477	P=0.022N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node: Mediastinal
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	4/9 (44%)	3/7 (43%)	1/7 (14%)	2/8 (25%)
POLY-3 RATE (b)	4/8.52	3/4.94	1/5.65	2/7.40
POLY-3 PERCENT (g)	47%	60.8%	17.7%	27%
TERMINAL (d)	0/3 (0%)	1/1 (100%)	1/4 (25%)	2/3 (67%)
FIRST INCIDENCE	575	589	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.241N	P=0.529	P=0.291N	P=0.385N
POLY 1.5	P=0.247N	P=0.574	P=0.262N	P=0.379N
POLY 6	P=0.239N	P=0.453	P=0.334N	P=0.402N
COCH-ARM / FISHERS	P=0.272N	P=0.671N	P=0.231N	P=0.373N
MAX-ISO-POLY-3	P=0.185N	P=0.347	P=0.164N	P=0.222N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Lymph Node: Mediastinal
 Pigmentation**

LESION RATES

OVERALL (a)	2/9 (22%)	3/7 (43%)	2/7 (29%)	1/8 (13%)
POLY-3 RATE (b)	2/7.91	3/4.94	2/5.65	1/7.40
POLY-3 PERCENT (g)	25.3%	60.8%	35.4%	13.5%
TERMINAL (d)	1/3 (33%)	1/1 (100%)	2/4 (50%)	1/3 (33%)
FIRST INCIDENCE	666	589	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.248N	P=0.249	P=0.576	P=0.525N
POLY 1.5	P=0.265N	P=0.274	P=0.590	P=0.532N
POLY 6	P=0.229N	P=0.209	P=0.557	P=0.519N
COCH-ARM / FISHERS	P=0.290N	P=0.365	P=0.608	P=0.547N
MAX-ISO-POLY-3	P=0.212N	P=0.136	P=0.362	P=0.291N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Lymph Node: Pancreatic Hemorrhage

LESION RATES

OVERALL (a)	2/9 (22%)	2/7 (29%)	0/7 (0%)	1/8 (13%)
POLY-3 RATE (b)	2/7.68	2/5.85	0/5.65	1/7.57
POLY-3 PERCENT (g)	26.1%	34.2%	0%	13.2%
TERMINAL (d)	2/3 (67%)	0/1 (0%)	0/4 (0%)	0/3 (0%)
FIRST INCIDENCE	729 (T)	59	---	687

STATISTICAL TESTS

POLY 3	P=0.339N	P=0.605	P=0.295N	P=0.505N
POLY 1.5	P=0.354N	P=0.607	P=0.291N	P=0.522N
POLY 6	P=0.314N	P=0.600	P=0.297N	P=0.481N
COCH-ARM / FISHERS	P=0.368N	P=0.608	P=0.300N	P=0.547N
MAX-ISO-POLY-3	P=0.225N	P=0.384	P=0.113N	P=0.277N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Mammary Gland
 Hyperplasia**

LESION RATES

OVERALL (a)	49/50 (98%)	46/50 (92%)	45/50 (90%)	34/50 (68%)
POLY-3 RATE (b)	49/50.00	46/48.47	45/48.22	34/47.30
POLY-3 PERCENT (g)	98%	94.9%	93.3%	71.9%
TERMINAL (d)	29/30 (97%)	34/36 (94%)	40/42 (95%)	26/36 (72%)
FIRST INCIDENCE	404	585	474	563

STATISTICAL TESTS

POLY 3	P<0.001N**	P=0.383N	P=0.249N	P<0.001N**
POLY 1.5	P<0.001N**	P=0.340N	P=0.210N	P<0.001N**
POLY 6	P<0.001N**	P=0.435N	P=0.314N	P<0.001N**
COCH-ARM / FISHERS	P<0.001N**	P=0.181N	P=0.102N	P<0.001N**
MAX-ISO-POLY-3	P<0.001N**	P=0.199N	P=0.119N	P<0.001N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Mesentery
 Accessory Spleen

LESION RATES

OVERALL (a)	0/9 (0%)	2/7 (29%)	2/4 (50%)	1/2 (50%)
POLY-3 RATE (b)	0/8.67	2/6.60	2/4.00	1/2.00
POLY-3 PERCENT (g)	0%	30.3%	50%	50%
TERMINAL (d)	0/6 (0%)	1/4 (25%)	2/4 (50%)	1/2 (50%)
FIRST INCIDENCE	---	653	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.117	P=0.156	P=0.042*	P=0.150
POLY 1.5	P=0.112	P=0.159	P=0.040*	P=0.148
POLY 6	P=0.126	P=0.152	P=0.045*	P=0.154
COCH-ARM / FISHERS	P=0.117	P=0.175	P=0.077	P=0.182
MAX-ISO-POLY-3	P=0.170	P=0.045*	P=0.010**	P=0.017*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Mesentery
 Hemorrhage**

LESION RATES

OVERALL (a)	0/9 (0%)	0/7 (0%)	0/4 (0%)	0/2 (0%)
POLY-3 RATE (b)	0/8.67	0/6.32	0/4.00	0/2.00
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/6 (0%)	0/4 (0%)	0/4 (0%)	0/2 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Mesentery: Fat
 Necrosis

LESION RATES

OVERALL (a)	9/9 (100%)	5/7 (71%)	3/4 (75%)	1/2 (50%)
POLY-3 RATE (b)	9/9.00	5/6.72	3/4.00	1/2.00
POLY-3 PERCENT (g)	100%	74.4%	75%	50%
TERMINAL (d)	6/6 (100%)	3/4 (75%)	3/4 (75%)	1/2 (50%)
FIRST INCIDENCE	682	642	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.142N	P=0.195N	P=0.329N	P=0.146N
POLY 1.5	P=0.152N	P=0.177N	P=0.329N	P=0.146N
POLY 6	P=0.128N	P=0.234N	P=0.329N	P=0.146N
COCH-ARM / FISHERS	P=0.165N	P=0.175N	P=0.308N	P=0.182N
MAX-ISO-POLY-3	P=0.137N	P=0.052N	P=0.088N	P=0.017N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Nose
 Foreign Body

LESION RATES

OVERALL (a)	4/50 (8%)	3/50 (6%)	2/50 (4%)	2/50 (4%)
POLY-3 RATE (b)	4/45.22	3/45.02	2/45.91	2/46.07
POLY-3 PERCENT (g)	8.9%	6.7%	4.4%	4.3%
TERMINAL (d)	1/30 (3%)	2/36 (6%)	2/42 (5%)	2/36 (6%)
FIRST INCIDENCE	663	709	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.288N	P=0.502N	P=0.330N	P=0.329N
POLY 1.5	P=0.293N	P=0.505N	P=0.338N	P=0.335N
POLY 6	P=0.281N	P=0.501N	P=0.318N	P=0.320N
COCH-ARM / FISHERS	P=0.295N	P=0.500N	P=0.339N	P=0.339N
MAX-ISO-POLY-3	P=0.303N	P=0.349N	P=0.197N	P=0.196N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose
 Inflammation Chronic**

LESION RATES

OVERALL (a)	2/50 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	2/45.19	0/44.94	1/45.91	2/46.07
POLY-3 PERCENT (g)	4.4%	0%	2.2%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	1/42 (2%)	2/36 (6%)
FIRST INCIDENCE	663	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.420	P=0.238N	P=0.495N	P=0.687N
POLY 1.5	P=0.416	P=0.239N	P=0.500N	P=0.692N
POLY 6	P=0.426	P=0.238N	P=0.485N	P=0.680N
COCH-ARM / FISHERS	P=0.412	P=0.247N	P=0.500N	P=0.691N
MAX-ISO-POLY-3	P=0.419N	P=0.077N	P=0.277N	P=0.491N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose: Respiratory Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.94	0/44.94	0/45.91	1/46.07
POLY-3 PERCENT (g)	2.2%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	709	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.549	P=0.500N	P=0.496N	P=0.755N
POLY 1.5	P=0.546	P=0.501N	P=0.499N	P=0.759N
POLY 6	P=0.552	P=0.499N	P=0.490N	P=0.750N
COCH-ARM / FISHERS	P=0.544	P=0.500N	P=0.500N	P=0.753N
MAX-ISO-POLY-3	P=0.405N	P=0.158N	P=0.158N	P=0.492N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Nose: Respiratory Epithelium
 Metaplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Ovary
 Cyst**

LESION RATES

OVERALL (a)	8/50 (16%)	5/50 (10%)	14/50 (28%)	8/49 (16%)
POLY-3 RATE (b)	8/45.88	5/45.02	14/47.41	8/45.39
POLY-3 PERCENT (g)	17.4%	11.1%	29.5%	17.6%
TERMINAL (d)	5/30 (17%)	4/36 (11%)	11/42 (26%)	8/36 (22%)
FIRST INCIDENCE	537	709	474	729 (T)

STATISTICAL TESTS

POLY 3	P=0.429	P=0.287N	P=0.128	P=0.599
POLY 1.5	P=0.415	P=0.287N	P=0.117	P=0.589
POLY 6	P=0.451	P=0.288N	P=0.147	P=0.604N
COCH-ARM / FISHERS	P=0.408	P=0.277N	P=0.114	P=0.590
MAX-ISO-POLY-3	P=0.202	P=0.197N	P=0.087	P=0.490

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas
 Atrophy**

LESION RATES

OVERALL (a)	10/49 (20%)	17/50 (34%)	17/50 (34%)	14/50 (28%)
POLY-3 RATE (b)	10/44.46	17/46.71	17/46.45	14/46.95
POLY-3 PERCENT (g)	22.5%	36.4%	36.6%	29.8%
TERMINAL (d)	6/30 (20%)	11/36 (31%)	16/42 (38%)	9/36 (25%)
FIRST INCIDENCE	666	585	563	563

STATISTICAL TESTS

POLY 3	P=0.496	P=0.108	P=0.105	P=0.289
POLY 1.5	P=0.473	P=0.099	P=0.097	P=0.270
POLY 6	P=0.526	P=0.122	P=0.120	P=0.314
COCH-ARM / FISHERS	P=0.456	P=0.098	P=0.098	P=0.259
MAX-ISO-POLY-3	P=0.190	P=0.075	P=0.072	P=0.219

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas
 Cyst**

LESION RATES

OVERALL (a)	4/49 (8%)	10/50 (20%)	6/50 (12%)	13/50 (26%)
POLY-3 RATE (b)	4/44.44	10/45.41	6/45.91	13/46.28
POLY-3 PERCENT (g)	9%	22%	13.1%	28.1%
TERMINAL (d)	2/30 (7%)	9/36 (25%)	6/42 (14%)	11/36 (31%)
FIRST INCIDENCE	575	589	729 (T)	687

STATISTICAL TESTS

POLY 3	P=0.032*	P=0.077	P=0.390	P=0.017*
POLY 1.5	P=0.030*	P=0.076	P=0.381	P=0.016*
POLY 6	P=0.035*	P=0.078	P=0.407	P=0.019*
COCH-ARM / FISHERS	P=0.031*	P=0.080	P=0.383	P=0.017*
MAX-ISO-POLY-3	P=0.015*	P=0.043*	P=0.272	P=0.010**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pancreas: Acinus
 Cytoplasmic Alteration**

LESION RATES

OVERALL (a)	1/49 (2%)	1/50 (2%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	1/44.40	1/44.94	0/45.91	1/46.12
POLY-3 PERCENT (g)	2.3%	2.2%	0%	2.2%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	729 (T)	---	716

STATISTICAL TESTS

POLY 3	P=0.684N	P=0.758N	P=0.493N	P=0.752N
POLY 1.5	P=0.683	P=0.758N	P=0.496N	P=0.755N
POLY 6	P=0.682N	P=0.758N	P=0.488N	P=0.748N
COCH-ARM / FISHERS	P=0.683	P=0.747N	P=0.495N	P=0.747N
MAX-ISO-POLY-3	P=0.531N	P=0.496N	P=0.157N	P=0.488N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Pancreas: Acinus
 Hyperplasia Focal

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/43.89	1/44.94	1/45.91	0/46.07
POLY-3 PERCENT (g)	0%	2.2%	2.2%	0%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	1/42 (2%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.534N	P=0.505	P=0.509	(e)
POLY 1.5	P=0.539N	P=0.503	P=0.505	(e)
POLY 6	P=0.527N	P=0.507	P=0.516	(e)
COCH-ARM / FISHERS	P=0.541N	P=0.505	P=0.505	(e)
MAX-ISO-POLY-3	P=0.413N	P=0.163	P=0.168	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Angiectasis**

LESION RATES

OVERALL (a)	8/50 (16%)	7/50 (14%)	3/50 (6%)	8/50 (16%)
POLY-3 RATE (b)	8/46.27	7/45.52	3/45.91	8/46.50
POLY-3 PERCENT (g)	17.3%	15.4%	6.5%	17.2%
TERMINAL (d)	2/30 (7%)	5/36 (14%)	3/42 (7%)	6/36 (17%)
FIRST INCIDENCE	575	639	729 (T)	641

STATISTICAL TESTS

POLY 3	P=0.514	P=0.514N	P=0.101N	P=0.603N
POLY 1.5	P=0.507	P=0.513N	P=0.103N	P=0.605
POLY 6	P=0.523	P=0.517N	P=0.097N	P=0.595N
COCH-ARM / FISHERS	P=0.504	P=0.500N	P=0.100N	P=0.607N
MAX-ISO-POLY-3	P=0.369N	P=0.401N	P=0.055N	P=0.495N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Cyst**

LESION RATES

OVERALL (a)	30/50 (60%)	23/50 (46%)	27/50 (54%)	20/50 (40%)
POLY-3 RATE (b)	30/47.12	23/46.97	27/47.41	20/47.36
POLY-3 PERCENT (g)	63.7%	49%	57%	42.2%
TERMINAL (d)	18/30 (60%)	16/36 (44%)	24/42 (57%)	13/36 (36%)
FIRST INCIDENCE	575	585	474	575

STATISTICAL TESTS

POLY 3	P=0.049N*	P=0.105N	P=0.322N	P=0.027N*
POLY 1.5	P=0.055N	P=0.114N	P=0.345N	P=0.031N*
POLY 6	P=0.043N*	P=0.099N	P=0.300N	P=0.023N*
COCH-ARM / FISHERS	P=0.062N	P=0.115N	P=0.343N	P=0.036N*
MAX-ISO-POLY-3	P=0.027N*	P=0.072N	P=0.251N	P=0.016N*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Distalis
 Hyperplasia Focal**

LESION RATES

OVERALL (a)	13/50 (26%)	4/50 (8%)	12/50 (24%)	9/50 (18%)
POLY-3 RATE (b)	13/47.10	4/44.94	12/45.91	9/46.23
POLY-3 PERCENT (g)	27.6%	8.9%	26.1%	19.5%
TERMINAL (d)	5/30 (17%)	4/36 (11%)	12/42 (29%)	7/36 (19%)
FIRST INCIDENCE	575	729 (T)	729 (T)	701

STATISTICAL TESTS

POLY 3	P=0.500N	P=0.018N*	P=0.530N	P=0.248N
POLY 1.5	P=0.507N	P=0.017N*	P=0.526N	P=0.247N
POLY 6	P=0.489N	P=0.021N*	P=0.532N	P=0.251N
COCH-ARM / FISHERS	P=0.511N	P=0.016N*	P=0.500N	P=0.235N
MAX-ISO-POLY-3	P=0.211N	P=0.010N**	P=0.436N	P=0.180N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Intermedia
 Angiectasis**

LESION RATES

OVERALL (a)	1/50 (2%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	1/45.37	1/44.94	0/45.91	2/46.18
POLY-3 PERCENT (g)	2.2%	2.2%	0%	4.3%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	1/36 (3%)
FIRST INCIDENCE	575	729 (T)	---	701

STATISTICAL TESTS

POLY 3	P=0.344	P=0.759	P=0.498N	P=0.506
POLY 1.5	P=0.341	P=0.758	P=0.501N	P=0.501
POLY 6	P=0.348	P=0.759	P=0.492N	P=0.514
COCH-ARM / FISHERS	P=0.338	P=0.753N	P=0.500N	P=0.500
MAX-ISO-POLY-3	P=0.288	P=0.496	P=0.159N	P=0.287

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Pituitary Gland: Pars Intermedia
 Cyst**

LESION RATES

OVERALL (a)	3/50 (6%)	0/50 (0%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	3/44.97	0/44.94	0/45.91	2/46.07
POLY-3 PERCENT (g)	6.7%	0%	0%	4.3%
TERMINAL (d)	2/30 (7%)	0/36 (0%)	0/42 (0%)	2/36 (6%)
FIRST INCIDENCE	703	---	---	729 (T)

STATISTICAL TESTS

POLY 3	P=0.585	P=0.119N	P=0.115N	P=0.489N
POLY 1.5	P=0.583	P=0.120N	P=0.118N	P=0.497N
POLY 6	P=0.589	P=0.117N	P=0.110N	P=0.478N
COCH-ARM / FISHERS	P=0.579	P=0.121N	P=0.121N	P=0.500N
MAX-ISO-POLY-3	P=0.105N	P=0.038N*	P=0.038N*	P=0.316N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Salivary Glands
 Atrophy**

LESION RATES

OVERALL (a)	7/50 (14%)	0/50 (0%)	5/50 (10%)	3/50 (6%)
POLY-3 RATE (b)	7/45.95	0/44.94	5/45.91	3/46.12
POLY-3 PERCENT (g)	15.2%	0%	10.9%	6.5%
TERMINAL (d)	2/30 (7%)	0/36 (0%)	5/42 (12%)	2/36 (6%)
FIRST INCIDENCE	575	---	729 (T)	716

STATISTICAL TESTS

POLY 3	P=0.367N	P=0.008N**	P=0.380N	P=0.156N
POLY 1.5	P=0.374N	P=0.008N**	P=0.386N	P=0.159N
POLY 6	P=0.357N	P=0.008N**	P=0.368N	P=0.151N
COCH-ARM / FISHERS	P=0.382N	P=0.006N**	P=0.380N	P=0.159N
MAX-ISO-POLY-3	P=0.077N	P=0.003N**	P=0.270N	P=0.089N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Cyst Epithelial Inclusion**

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/43.94	1/46.63	0/46.07
POLY-3 PERCENT (g)	0%	0%	2.1%	0%
TERMINAL (d)	0/30 (0%)	0/35 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	474	---

STATISTICAL TESTS

POLY 3	P=0.784N	(e)	P=0.508	(e)
POLY 1.5	P=0.786N	(e)	P=0.503	(e)
POLY 6	P=0.780N	(e)	P=0.515	(e)
COCH-ARM / FISHERS	P=0.788N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.400	(e)	P=0.168	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Skin
 Edema

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	0/43.94	0/45.91	1/46.18
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/35 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	701

STATISTICAL TESTS

POLY 3	P=0.217	(e)	(e)	P=0.506
POLY 1.5	P=0.214	(e)	(e)	P=0.502
POLY 6	P=0.221	(e)	(e)	P=0.511
COCH-ARM / FISHERS	P=0.212	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.137	(e)	(e)	P=0.166

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Hyperkeratosis**

LESION RATES

OVERALL (a)	1/50 (2%)	0/49 (0%)	1/50 (2%)	1/50 (2%)
POLY-3 RATE (b)	1/44.92	0/43.94	1/45.91	1/46.07
POLY-3 PERCENT (g)	2.2%	0%	2.2%	2.2%
TERMINAL (d)	0/30 (0%)	0/35 (0%)	1/42 (2%)	1/36 (3%)
FIRST INCIDENCE	716	---	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.553	P=0.504N	P=0.756N	P=0.755N
POLY 1.5	P=0.548	P=0.505N	P=0.760N	P=0.759N
POLY 6	P=0.560	P=0.503N	P=0.749N	P=0.750N
COCH-ARM / FISHERS	P=0.544	P=0.505N	P=0.753N	P=0.753N
MAX-ISO-POLY-3	P=0.554	P=0.163N	P=0.493N	P=0.492N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin
 Inflammation Chronic**

LESION RATES

OVERALL (a)	0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/43.94	1/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	2.2%	0%
TERMINAL (d)	0/30 (0%)	0/35 (0%)	1/42 (2%)	0/36 (0%)
FIRST INCIDENCE	---	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.784N	(e)	P=0.505	(e)
POLY 1.5	P=0.786N	(e)	P=0.501	(e)
POLY 6	P=0.780N	(e)	P=0.511	(e)
COCH-ARM / FISHERS	P=0.788N	(e)	P=0.500	(e)
MAX-ISO-POLY-3	P=0.398	(e)	P=0.164	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Skin: Epidermis
 Hyperplasia**

LESION RATES

OVERALL (a)	1/50 (2%)	0/49 (0%)	1/50 (2%)	0/50 (0%)
POLY-3 RATE (b)	1/44.92	0/43.94	1/45.91	0/46.07
POLY-3 PERCENT (g)	2.2%	0%	2.2%	0%
TERMINAL (d)	0/30 (0%)	0/35 (0%)	1/42 (2%)	0/36 (0%)
FIRST INCIDENCE	716	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.449N	P=0.504N	P=0.756N	P=0.495N
POLY 1.5	P=0.451N	P=0.505N	P=0.760N	P=0.498N
POLY 6	P=0.446N	P=0.503N	P=0.749N	P=0.490N
COCH-ARM / FISHERS	P=0.454N	P=0.505N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.258N	P=0.163N	P=0.493N	P=0.158N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

Spleen
 Accessory Spleen

LESION RATES

OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	2/43.89	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	4.6%	0%	0%	0%
TERMINAL (d)	2/30 (7%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	729 (T)	---	---	---

STATISTICAL TESTS

POLY 3	P=0.217N	P=0.232N	P=0.227N	P=0.226N
POLY 1.5	P=0.216N	P=0.234N	P=0.232N	P=0.231N
POLY 6	P=0.218N	P=0.229N	P=0.220N	P=0.221N
COCH-ARM / FISHERS	P=0.218N	P=0.242N	P=0.242N	P=0.242N
MAX-ISO-POLY-3	P=0.033N*	P=0.075N	P=0.075N	P=0.075N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Fibrosis**

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	2/50 (4%)
POLY-3 RATE (b)	0/43.89	1/45.28	0/45.91	2/46.72
POLY-3 PERCENT (g)	0%	2.2%	0%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	635	---	563

STATISTICAL TESTS

POLY 3	P=0.158	P=0.506	(e)	P=0.251
POLY 1.5	P=0.154	P=0.504	(e)	P=0.246
POLY 6	P=0.163	P=0.509	(e)	P=0.259
COCH-ARM / FISHERS	P=0.151	P=0.505	(e)	P=0.253
MAX-ISO-POLY-3	P=0.095	P=0.165	(e)	P=0.089

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hematopoietic Cell Proliferation**

LESION RATES

OVERALL (a)	37/49 (76%)	34/50 (68%)	42/50 (84%)	35/50 (70%)
POLY-3 RATE (b)	37/48.31	34/46.99	42/48.48	35/47.52
POLY-3 PERCENT (g)	76.6%	72.4%	86.6%	73.7%
TERMINAL (d)	22/30 (73%)	29/36 (81%)	36/42 (86%)	29/36 (81%)
FIRST INCIDENCE	404	59	474	563

STATISTICAL TESTS

POLY 3	P=0.480N	P=0.403N	P=0.151	P=0.462N
POLY 1.5	P=0.480N	P=0.339N	P=0.151	P=0.433N
POLY 6	P=0.476N	P=0.514N	P=0.159	P=0.501N
COCH-ARM / FISHERS	P=0.414N	P=0.272N	P=0.212	P=0.349N
MAX-ISO-POLY-3	P=0.399	P=0.316N	P=0.098	P=0.369N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hemorrhage**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.89	0/44.94	0/45.91	1/46.08
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	726

STATISTICAL TESTS

POLY 3	P=0.217	(e)	(e)	P=0.510
POLY 1.5	P=0.214	(e)	(e)	P=0.506
POLY 6	P=0.220	(e)	(e)	P=0.515
COCH-ARM / FISHERS	P=0.212	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.140	(e)	(e)	P=0.169

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Hyperplasia Lymphoid**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/43.89	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Infiltration Cellular Mixed Cell**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	0/43.89	0/44.94	0/45.91	3/46.23
POLY-3 PERCENT (g)	0%	0%	0%	6.5%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	2/36 (6%)
FIRST INCIDENCE	---	---	---	687

STATISTICAL TESTS

POLY 3	P=0.009**	(e)	(e)	P=0.128
POLY 1.5	P=0.009**	(e)	(e)	P=0.125
POLY 6	P=0.009**	(e)	(e)	P=0.134
COCH-ARM / FISHERS	P=0.009**	(e)	(e)	P=0.125
MAX-ISO-POLY-3	P=0.013*	(e)	(e)	P=0.045*

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Spleen
 Necrosis**

LESION RATES

OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/43.89	0/44.94	0/45.91	1/46.08
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	726

STATISTICAL TESTS

POLY 3	P=0.217	(e)	(e)	P=0.510
POLY 1.5	P=0.214	(e)	(e)	P=0.506
POLY 6	P=0.220	(e)	(e)	P=0.515
COCH-ARM / FISHERS	P=0.212	(e)	(e)	P=0.505
MAX-ISO-POLY-3	P=0.140	(e)	(e)	P=0.169

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach
 Edema**

LESION RATES

OVERALL (a)	0/50 (0%)	1/50 (2%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.86	1/45.26	1/46.63	2/46.62
POLY-3 PERCENT (g)	0%	2.2%	2.1%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	642	474	575

STATISTICAL TESTS

POLY 3	P=0.198	P=0.502	P=0.508	P=0.246
POLY 1.5	P=0.192	P=0.500	P=0.503	P=0.241
POLY 6	P=0.206	P=0.505	P=0.515	P=0.253
COCH-ARM / FISHERS	P=0.187	P=0.500	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.137	P=0.161	P=0.168	P=0.084

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach
 Ulcer**

LESION RATES

OVERALL (a)	2/50 (4%)	2/50 (4%)	0/50 (0%)	3/50 (6%)
POLY-3 RATE (b)	2/45.88	2/45.60	0/45.91	3/46.67
POLY-3 PERCENT (g)	4.4%	4.4%	0%	6.4%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	575	635	---	575

STATISTICAL TESTS

POLY 3	P=0.378	P=0.692	P=0.237N	P=0.508
POLY 1.5	P=0.374	P=0.690	P=0.239N	P=0.502
POLY 6	P=0.383	P=0.694N	P=0.233N	P=0.517
COCH-ARM / FISHERS	P=0.371	P=0.691N	P=0.247N	P=0.500
MAX-ISO-POLY-3	P=0.309	P=0.497	P=0.076N	P=0.332

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Forestomach: Epithelium
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	0/44.86	2/45.26	1/46.63	2/46.16
POLY-3 PERCENT (g)	0%	4.4%	2.1%	4.3%
TERMINAL (d)	0/30 (0%)	1/36 (3%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	642	474	716

STATISTICAL TESTS

POLY 3	P=0.318	P=0.239	P=0.508	P=0.244
POLY 1.5	P=0.311	P=0.237	P=0.503	P=0.239
POLY 6	P=0.328	P=0.242	P=0.515	P=0.250
COCH-ARM / FISHERS	P=0.307	P=0.247	P=0.500	P=0.247
MAX-ISO-POLY-3	P=0.173	P=0.078	P=0.168	P=0.082

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular
 Erosion**

LESION RATES

OVERALL (a)	4/50 (8%)	2/50 (4%)	1/50 (2%)	2/50 (4%)
POLY-3 RATE (b)	4/45.42	2/45.48	1/46.19	2/46.44
POLY-3 PERCENT (g)	8.8%	4.4%	2.2%	4.3%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	682	653	652	641

STATISTICAL TESTS

POLY 3	P=0.352N	P=0.337N	P=0.174N	P=0.327N
POLY 1.5	P=0.356N	P=0.340N	P=0.179N	P=0.334N
POLY 6	P=0.347N	P=0.333N	P=0.166N	P=0.318N
COCH-ARM / FISHERS	P=0.359N	P=0.339N	P=0.181N	P=0.339N
MAX-ISO-POLY-3	P=0.180N	P=0.200N	P=0.082N	P=0.196N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular
 Ulcer**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	1/46.58
POLY-3 PERCENT (g)	0%	0%	0%	2.2%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	575

STATISTICAL TESTS

POLY 3	P=0.217	(e)	(e)	P=0.507
POLY 1.5	P=0.214	(e)	(e)	P=0.503
POLY 6	P=0.221	(e)	(e)	P=0.514
COCH-ARM / FISHERS	P=0.210	(e)	(e)	P=0.500
MAX-ISO-POLY-3	P=0.139	(e)	(e)	P=0.168

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
Goldenseal root powder
CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
Time Report Requested: 08:34:31
First Dose M/F: 04/21/03 / 04/21/03
Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Stomach, Glandular: Epithelium
Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	0/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	0%	0%	0%
TERMINAL (d)	0/30 (0%)	0/36 (0%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	---	---	---

STATISTICAL TESTS

POLY 3	(e)	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus
 Atrophy**

LESION RATES

OVERALL (a)	0/49 (0%)	1/50 (2%)	0/49 (0%)	1/49 (2%)
POLY-3 RATE (b)	0/43.86	1/45.94	0/45.44	1/45.58
POLY-3 PERCENT (g)	0%	2.2%	0%	2.2%
TERMINAL (d)	0/29 (0%)	0/36 (0%)	0/42 (0%)	0/35 (0%)
FIRST INCIDENCE	---	59	---	575

STATISTICAL TESTS

POLY 3	P=0.464	P=0.509	(e)	P=0.508
POLY 1.5	P=0.458	P=0.507	(e)	P=0.503
POLY 6	P=0.472	P=0.511	(e)	P=0.514
COCH-ARM / FISHERS	P=0.454	P=0.505	(e)	P=0.500
MAX-ISO-POLY-3	P=0.271	P=0.169	(e)	P=0.168

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thymus
 Cyst**

LESION RATES

OVERALL (a)	1/49 (2%)	0/50 (0%)	1/49 (2%)	0/49 (0%)
POLY-3 RATE (b)	1/43.86	0/44.94	1/45.44	0/45.07
POLY-3 PERCENT (g)	2.3%	0%	2.2%	0%
TERMINAL (d)	1/29 (3%)	0/36 (0%)	1/42 (2%)	0/35 (0%)
FIRST INCIDENCE	729 (T)	---	729 (T)	---

STATISTICAL TESTS

POLY 3	P=0.454N	P=0.495N	P=0.753N	P=0.495N
POLY 1.5	P=0.456N	P=0.497N	P=0.758N	P=0.498N
POLY 6	P=0.450N	P=0.493N	P=0.744N	P=0.489N
COCH-ARM / FISHERS	P=0.458N	P=0.495N	P=0.753N	P=0.500N
MAX-ISO-POLY-3	P=0.256N	P=0.157N	P=0.489N	P=0.158N

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: C-Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	17/50 (34%)	5/50 (10%)	6/50 (12%)	5/50 (10%)
POLY-3 RATE (b)	17/45.70	5/44.94	6/46.14	5/46.17
POLY-3 PERCENT (g)	37.2%	11.1%	13%	10.8%
TERMINAL (d)	14/30 (47%)	5/36 (14%)	5/42 (12%)	3/36 (8%)
FIRST INCIDENCE	575	729 (T)	666	716

STATISTICAL TESTS

POLY 3	P=0.015N*	P=0.003N**	P=0.006N**	P=0.002N**
POLY 1.5	P=0.016N*	P=0.003N**	P=0.007N**	P=0.003N**
POLY 6	P=0.013N*	P=0.003N**	P=0.004N**	P=0.002N**
COCH-ARM / FISHERS	P=0.021N*	P=0.004N**	P=0.008N**	P=0.004N**
MAX-ISO-POLY-3	P<0.001N**	P<0.001N**	P=0.003N**	P<0.001N**

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicle
 Cyst**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	2/50 (4%)	1/50 (2%)
POLY-3 RATE (b)	0/44.86	2/44.94	2/45.91	1/46.07
POLY-3 PERCENT (g)	0%	4.5%	4.4%	2.2%
TERMINAL (d)	0/30 (0%)	2/36 (6%)	2/42 (5%)	1/36 (3%)
FIRST INCIDENCE	---	729 (T)	729 (T)	729 (T)

STATISTICAL TESTS

POLY 3	P=0.610	P=0.237	P=0.242	P=0.505
POLY 1.5	P=0.602	P=0.236	P=0.238	P=0.502
POLY 6	P=0.623	P=0.239	P=0.250	P=0.510
COCH-ARM / FISHERS	P=0.597	P=0.247	P=0.247	P=0.500
MAX-ISO-POLY-3	P=0.239	P=0.076	P=0.081	P=0.165

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS
 Goldenseal root powder
 CAS Number: GOLDENSEALRT

Date Report Requested: 08/15/2008
 Time Report Requested: 08:34:31
 First Dose M/F: 04/21/03 / 04/21/03
 Lab: SRI

**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Thyroid Gland: Follicular Cell
 Hyperplasia**

LESION RATES

OVERALL (a)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
POLY-3 RATE (b)	0/44.86	2/44.94	0/45.91	0/46.07
POLY-3 PERCENT (g)	0%	4.5%	0%	0%
TERMINAL (d)	0/30 (0%)	2/36 (6%)	0/42 (0%)	0/36 (0%)
FIRST INCIDENCE	---	729 (T)	---	---

STATISTICAL TESTS

POLY 3	P=0.366N	P=0.237	(e)	(e)
POLY 1.5	P=0.369N	P=0.236	(e)	(e)
POLY 6	P=0.362N	P=0.239	(e)	(e)
COCH-ARM / FISHERS	P=0.370N	P=0.247	(e)	(e)
MAX-ISO-POLY-3	P=0.254N	P=0.076	(e)	(e)

TDMS No. 99007 - 05
 Test Type: CHRONIC
 Route: DOSED FEED
 Species/Strain: RATS/F 344

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**STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344)
 TERMINAL SACRIFICE AT 105 WEEKS**

DOSE	Females			
	0 PPM	3000 PPM	9000 PPM	25000 PPM

**Uterus
 Hyperplasia Cystic**

LESION RATES

OVERALL (a)	8/50 (16%)	9/50 (18%)	14/50 (28%)	13/50 (26%)
POLY-3 RATE (b)	8/45.45	9/45.31	14/47.21	13/46.12
POLY-3 PERCENT (g)	17.6%	19.9%	29.7%	28.2%
TERMINAL (d)	6/30 (20%)	8/36 (22%)	11/42 (26%)	12/36 (33%)
FIRST INCIDENCE	575	627	565	716

STATISTICAL TESTS

POLY 3	P=0.140	P=0.497	P=0.130	P=0.168
POLY 1.5	P=0.134	P=0.493	P=0.117	P=0.162
POLY 6	P=0.151	P=0.502	P=0.154	P=0.179
COCH-ARM / FISHERS	P=0.133	P=0.500	P=0.114	P=0.163
MAX-ISO-POLY-3	P=0.166	P=0.390	P=0.090	P=0.114

TDMS No. 99007 - 05
Test Type: CHRONIC
Route: DOSED FEED
Species/Strain: RATS/F 344

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LEGEND

- (a) Number of tumor-bearing animals/number of animals examined at site.
 - (b) Number of tumor-bearing animals/Poly-3 number
 - (d) Observed incidence at terminal kill.
 - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death.
 - (e) Value of Statistic cannot be computed.
 - (g) Poly-3 adjusted lifetime tumor incidence.
 - (I) Interim sacrifice
 - (T) Terminal sacrifice
 - # Tumor rates based on numbers of animals necropsied.
 - * To the right of any statistical result, indicates significance at ($P \leq 0.05$).
 - ** To the right of any statistical result, indicates significance at ($P \leq 0.01$).
 - N Indicates a negative trend for all tests
- Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors.
The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

*** END OF REPORT ***