



Experimental Pathology Laboratories, Inc.

Ethyl-Tertiary-Butyl Ether
C00117/00117-64

**AMENDED
PATHOLOGY QUALITY ASSESSMENT
REVIEW AND PWG COORDINATOR'S REPORT
FOR
LIFETIME CARCINOGENICITY STUDY
OF ETHYL-TERTIARY-BUTYL ETHER (ETBE)
IN SPRAGUE-DAWLEY RATS**

CONDUCTED AT

**THE CANCER RESEARCH CENTER, EUROPEAN RAMAZZINI FOUNDATION
FOR ONCOLOGY AND ENVIRONMENTAL SCIENCES, BOLOGNA, ITALY**

CHEMICAL NO./TDMS NO.: C00117/00117-64

Submitted to:

National Toxicology Program
Research Triangle Park, NC 27709

Submitted by:

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October 6, 2011



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Experimental Pathology Laboratories, Inc.

NARRATIVE



Ethyl-Tertiary-Butyl Ether
C00117/00117-64

**AMENDED
PATHOLOGY QUALITY ASSESSMENT REVIEW AND
PATHOLOGY WORKING GROUP (PWG) COORDINATOR'S REPORT
FOR
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CHEMICAL/TDMS NO.: C00117/00117-64

Quality Assessment Review: February 7-18, 2011

Date of the Pathology Working Group: April 4 – 8, 2011

PWG Coordinator: Robert R. Maronpot, DVM, MPH

Quality Assessment Pathologist: [*] , DVM (EPL)

Study Diagnoses: Ramazzini Institute

PWG Participants:

Charles Clifford, DVM, PhD (Charles River)

Sabine Francke-Carroll, DVM, PhD (FDA)

Peter Greaves, MBChB (Leicester University)

Jerry F. Hardisty, DVM (EPL)

Peter C. Mann, DVM (EPL)

James B. Nold, DVM, PhD (Biotechnics)

PWG Observers:

Steven Mog, DVM, PhD (FDA)

Fiorella Belpoggi (Ramazzini Institute)

Morando Soffritti, MD (Ramazzini Institute)

Eva Tibaldi (Ramazzini Institute)

Laura Falcioni (Ramazzini Institute)

INTRODUCTION

This report by Experimental Pathology Laboratories, Inc. (EPL®) presents the results of the Quality Assessment Review and the Pathology Working Group (PWG) which reviewed glass slides subsequent to the Quality Assessment Review of the Ethyl-Tertiary-Butyl Ether (ETBE) study. The ETBE study was conducted by the Ramazzini Institute by gavage in extra virgin olive oil. The study started in 1993 and involved 360 rats.

EXPERIMENTAL DESIGN AND METHODS

The numbers of animals used and their allocation to dose groups are shown in Table 1.

Table 1 – Study Design for Bioassay on Ethyl-Tertiary-Butyl Ether (ETBE) Administered in Drinking Water to Male and Female Sprague-Dawley Rats

Group	Dose (g/kg/day)	No. Rat and Sex
I	1	60 Males & 60 Females
II	0.25	60 Males & 60 Females
III	0 ^a	60 Males & 60 Females

^aOlive Oil Alone

Results of study findings have been published previously by the Ramazzini Institute. The publication citations are as follows:

- Belpoggi, F., Soffritti, M., and Maltoni, C. (1999). Immunoblastic lymphomas in sprague-dawley rats following exposure to the gasoline oxygenated additives methyl-tertiary-butyl ether (MTBE) and ethyl-tertiary-butyl ether (ETBE): Early observations on their natural history. *Eur J Oncol* **4**, 563-572.
- Maltoni, C., Belpoggi, F., Soffritti, M., and Minardi, F. (1999). Comprehensive long-term experimental project of carcinogenicity bioassays on gasoline oxygenated additives: Plan and first report of results from the study on ethyl-tertiary butyl ether (ETBE). *Eur J Oncol* **4**, 493-508.



The peer review consisted of analysis of the Ramazzini Institute data and Quality Assessment (QA) of selected histopathology slides for the chronic lifetime study of ethyl-tertiary-butyl ether (ETBE) in Sprague-Dawley rats. The request was to conduct pathology peer review analysis of selected tumor types and preneoplastic and hyperplastic lesions in which the specific tumor type(s) was/were found increased by chemical treatment. The Quality Assessment Review of the pathology diagnoses was to include the examination of all sections of the oral cavity for hyperplastic and neoplastic changes from all male and female rats in all groups and all sections of the uterus and vagina for proliferative changes (hyperplasia, benign neoplasia and malignant neoplasms) for all female rats in all groups.

All slides with differences of opinion relating to the presence or absence of neoplasms in the tissues between the study and reviewing pathologist were identified for possible review by the Pathology Working Group.

Although all diagnoses reported by the Ramazzini pathologist were reviewed in each tissue, the focus of the technical approach was to achieve confirmation of proliferative lesions in the oral cavity, uterus, and vagina. The Quality Assessment (QA) review and included examination of the following:

- All sections of the oral cavity from all male and female rats in all groups for hyperplastic and neoplastic changes.
- All sections of uterus and vagina for hyperplastic and neoplastic lesions for all female rats in all groups.

Slide Review Work Sheets were used to document the results of the QA review. These work sheets list in animal number order tissues that were examined by the QA pathologist. In addition, these work sheets list the study pathologist's initial diagnosis for the tissues that were reviewed. The work sheets also record the QA pathologist's comments indicating agreement with the Ramazzini pathologist's diagnosis or a comment when a difference of opinion was noted.

The QA took place February 7 – 18, 2011 at the Ramazzini Institute. The number of slides examined during the QA review of the ETBE study is listed in Table 2.

Table 2. Number of Slides Reviewed During the QA Review

Group	Dose	Males	Females
		Slide Count	Slide Count
I	1.0 g/kg	305	471
II	0.25 g/kg	309	488
III	0 g/kg	304	442
	TOTAL	918	1401

The Pathology Working Group (PWG) met on April 6, 2011, and initially examined 36 slides from 12 rats across dose groups to determine the spectrum of proliferative changes in the oral cavity. These tissues were examined and the changes were discussed without voting on any diagnoses. The PWG Panel then examined a total of 139 slides from 80 rats in the ETBE study without knowledge of treatment group, sex (except for uterus & vagina slides), or previous diagnoses by the Ramazzini or QA pathologists. The PWG Panel examined representative slides from the following:

- All rats with a previous diagnosis of proliferative lesions including dysplasias, hyperplasias, and benign and malignant neoplasms affecting the oral mucosa and/or tongue.
- All proliferative, metaplastic, and neoplastic lesions in the uterus and vagina when there was a disagreement in diagnosis between the Ramazzini and QA pathologist.

The “Action to be Taken” column on the Slide Review Work Sheets is left blank because no post-PWG action was required.

RESULTS

All materials necessary for this review were readily available and well organized. All slides required to be examined by the QA pathologist were present. The histologic quality of the sections was considered to be very good with no deficiencies that interfered with the examination of the tissues present or the interpretation of

histopathologic changes that were present. Neither the occasional cases with tissue autolysis nor the use of alcohol fixation presented diagnostic difficulties.

Quality Assessment Review

During the QA review, original terminology used for oral cavity lesions was noted by the QA pathologist to be made consistent with NTP nomenclature and practice. Specifically, Ramazzini diagnoses of dysplasia in the oral cavity were diagnosed by the QA pathologist as minimal squamous hyperplasia and Ramazzini diagnoses of proliferation in the oral cavity were diagnosed as minimal hyperplasia or considered within normal limits by the QA pathologist.

Slide Review Work Sheets used to document the results of the QA review are presented in Appendices A and B. These work sheets list in animal number order tissues that were examined by the QA pathologist from EPL. These work sheets list the initial diagnoses for the tissues which were reviewed and the QA pathologist's agreement or difference of opinion. The QA review consisted of oral cavity and tongue for identification of non-neoplastic and neoplastic proliferative lesions from all male and female rats in all groups. Uterus and vagina from all females in all groups were examined to document the presence of proliferative non-neoplastic and neoplastic lesions. When the QA pathologist had a difference of opinion with the initial diagnosis, an alternative diagnosis was listed on the Slide Review Work Sheets. All differences of opinion between the Ramazzini and QA pathologists for proliferative lesions in oral cavity, on tongue, or in uterus and vagina were selected for review by the PWG. The QA pathologist agreed with all study pathologist diagnoses of inflammation, atrophy, cysts, fibrosis, and ulceration in the oral cavity. Small areas of reactive hyperplasia of periodontal epithelium associated with inflammation were seen adjacent to broken teeth in some rats. Mixed inflammatory cell infiltrates present in the uterine and vaginal mucosa were confirmed by the QA pathologist.

Pathology Working Group Review

The primary focus during the PWG review was to distinguish between neoplastic and non-neoplastic proliferative lesions in the oral cavity, on the tongue, and in the uterus and vagina. Some ancillary lesions such as inflammation and atrophy were not specifically or formally voted on by the PWG Panel. Curricula vitae for the PWG participants can be found in Appendix C.

The PWG Panel reviewed 139 slides representing 80 rats. Panel members independently reviewed each slide and noted their findings and personal comments on work sheets. Following examination of a small number of specific tissues from 10 to 20 rats, the PWG Coordinator recorded consensus diagnoses for the relevant tissues for each rat. Occasional differences of opinion among the PWG Panel were discussed and; if a consensus diagnosis was not initially achieved, the relevant slides were re-examined by each Panel member followed by further discussion until a consensus diagnosis was achieved. The most significant lesions of concern for this ETBE study involved diagnosis of epithelial tumors in the oral cavity and epithelial and mesenchymal neoplasms in the uterus and vagina.

Diagnostic criteria for oral cavity and uterine/vaginal lesions used by the Pathology Working Group Panel followed internationally accepted guidelines (International Classification of Rodent Tumours. Part I: The Rat. 9. Female Genital System. IARC Scientific Publication No. 122. 1997; International Classification of Rodent Tumours. Part I: The Rat. 10. Digestive System. IARC Scientific Publication No. 122.1997; and Pathology of the Fischer Rat, Edited by Boorman et al., 1990. Academic Press, New York).

Oral cavity and uterine/vaginal lesion incidences are summarized in Tables 3 and 4, respectively.

Table 3: Incidence of Lesions in the Oral Mucosa/Tongue

MALES						
No. of Rats per Group	0 g/kg/day		0.25 g/kg/day		1.0 g/kg/day	
	SD	QA/PWG	SD	QA/PWG	SD	QA/PWG
Hyperplasia, Squamous	0	14	0	28	0	18
Papilloma	1	0	0	0	2	0
Squamous Cell Carcinoma	0	0	0	0	1	0
FEMALES						
No. of Rats per Group	60		60		60	
	SD	QA/PWG	SD	QA/PWG	SD	QA/PWG
Hyperplasia, Squamous	0	9	0	29	0	28
Papilloma	1	0	1	0	1	0
Squamous Cell Carcinoma	0	0	0	0	1	0

SD = Ramazzini Institute Study Diagnoses

QA/PWG = Combined QA/PWG Panel Consensus

Table 4: Proliferative Lesions in the Uterus/Vagina

No. of Rats per Group	0 g/kg/day		0.25 g/kg/day		1.0 g/kg/day	
	SD	QA/PWG	SD	QA/PWG	SD	QA/PWG
Metaplasia, Squamous	3	3	3	6	4	5
Stromal Polyp	21	21	11	12	14	14
Carcinoma	1	0	1	1	0	0
Leiomyoma	0	0	0	0	2	3
Leiomyosarcoma	1	1	2	0	0	0
Schwannoma, Malignant	0	0	6	7	2	2
Histiocytic Sarcoma	1	1	0	0	1	1

SD = Ramazzini Institute Study Diagnoses

QA/PWG = Combined QA/PWG Panel Consensus

DISCUSSION

Oral cavity lesions documented in this study are typical age-related changes seen in chronic rat studies. The squamous hyperplasia was frequently in the oral cavity mucosa adjacent to teeth. Uterine stromal polyps and occasional mesenchymal tumors are common age-related changes seen in chronic rat studies. The incidence of malignant schwannomas in the 0.25 g/kg /day group is higher than what is usually seen.



Ethyl-Tertiary-Butyl Ether
C00117/00117-64

CONFLICT OF INTEREST STATEMENT

This statement is to certify that the person listed below, employed by Experimental Pathology Laboratories, Inc., participated in the QA review and Pathology Working Group (PWG) from the Lifetime Carcinogenicity Study of Ethyl-Tertiary-Butyl Ether (ETBE) in Sprague-Dawley Rats conducted at the Cancer Research Center, European Ramazzini Foundation for Oncology and Environmental Sciences. He has not been involved in any aspect of the study for any organization other than NTP which conducted the study nor the generation and/or evaluation of materials or data which were reviewed prior to the receipt of materials from the study lab. Hence, his participation in the PWG poses no apparent or actual conflict of interest.

A handwritten signature in black ink that reads "RR Maronpot".

ROBERT R. MARONPOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP, ABT
PWG Coordinator

A handwritten date in black ink that reads "6 Oct 2011".

DATE

RRM:asc



Ethyl-Tertiary-Butyl Ether
C00117/00117-64

REASON FOR CHANGE(S)

Pathology Quality Assessment
Review and PWG Coordinator's Report
For
Lifetime Carcinogenicity Study
of Ethyl-Tertiary-Butyl Ether (ETBE)
In Sprague-Dawley Rats

The amended report is being issued to include minor editorial changes to the text of the narrative portion of the final report submitted on July 22, 2011. No changes have been made to the Slide Review Work Sheets presented in Appendices A and B.

A handwritten signature in black ink that reads "RR Maronpot".

6 Oct 2011

ROBERT R. MARONPOT, D.V.M., M.S., M.P.H.
Diplomate, ACVP
Senior Veterinary Pathologist

DATE

RRM/asc



Experimental Pathology Laboratories, Inc.

SIGNATURE PAGE



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EPL Project No. 460-500-20

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Experimental Pathology Laboratories, Inc.

APPENDIX A
SLIDE REVIEW WORK SHEETS
MALE

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1061	M121255	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	TISSUE NORMAL	
1062	M121265	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)	TISSUE NORMAL	
1063	M121300	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1064	M121336	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1065	M121356	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1066	M122205	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1067	M122222	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 11)	NOT REVIEWED	
1068	M122258	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1069	M122282	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1070	M122294	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1071	M121384	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1072	M121408	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1073	M121417	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[ADJACENT TO TOOTH]	NOT REVIEWED	
1074	M122140	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)	NOT REVIEWED	
1075	M122165	5	ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	TISSUE NORMAL	
1076	M123036	5	ORAL MUCOSA - ATROPHY, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)[WITH HYPERKERATOSIS]	NOT REVIEWED	
1077	M123047	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	VEHICLE CONTROL			Dosage	VEHICLE CONTROL
Sex & Species	MALE	SD RATS	TMT 6	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1077	M123047	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1078	M123073	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1079	M123411	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1080	M123692	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1081	M120874	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1082	M120895	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	NOT PRESENT IN SECTION (8, 9, 11)	TISSUE NORMAL	
1083	M120924	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1084	M120948	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1085	M120958	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1086	M120973	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1086	M120973	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1087	M120965	6	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)	TISSUE NORMAL	
1088	M121008	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1089	M121036	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1090	M121046	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1091	M121062	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
1092	M121071	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1093	M121083	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
1094	M121097	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1095	M121110	6	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1096	M121939	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1097	M121951	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1098	M121986	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1099	M120999	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1100	M122000	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[NEAR TOOTH]	NOT REVIEWED	
1101	M122026	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1102	M122041	7	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	TISSUE NORMAL	
1103	M122053	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1104	M122065	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
1105	M122092	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1106	M122084	5	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
1107	M122110	5	ORAL MUCOSA - ATROPHY, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)	NOT REVIEWED	
1108	M122115	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1109	M122903	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1110	M122914	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1111	M122928	5	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	MALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1111	M122928 Cont'd	5		ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
1112	M122940	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1113	M122971	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[ADJACENT TO TOOTH]	NOT REVIEWED	
1114	M122982	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1115	M122990	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1116	M123294	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[ADJACENT TO TEETH]	NOT REVIEWED	
1117	M123307	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[ADJACENT TO TOOTH]	NOT REVIEWED	
1118	M123314	5				

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group VEHICLE CONTROL
Sex & Species MALE SD RATS

TMT 6

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage VEHICLE CONTROL
Sacrifice CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1118	M123314	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1119	M123327	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1120	M123339	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
261	M121240	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
262	M121249	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
263	M121287	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
264	M121322	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)[ADJACENT TO TOOTH SLIDE 10]	NOT REVIEWED	
265	M121345	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
			ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
266	M122178	5	ORAL MUCOSA - DYSPLASIA, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)[ADJACENT TO TOOTH SLIDE 10]	NOT REVIEWED	
267	M122216	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 0.25 G/KG
Sex & Species MALE SD RATS

TMT 4

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 0.25 G/KG
Sacrifice CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
268	M122246	6	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
269	M122270	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
270	M122275	9	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10, 11)	AGREE WITH REVIEWING PATHOLOGIST	
271	M121370	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
272	M121397	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
273	M121423	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
274	M121434	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	NOT PRESENT IN SECTION (9-11)	NOT REVIEWED	
275	M122153	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
276	M122305	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
276	M122305	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	TISSUE NORMAL	
277	M123029	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
278	M123063	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
279	M123085	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)[ADACENT TO TEETH SLIDE 10]	NOT REVIEWED	
280	M123425	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9-11)	TISSUE NORMAL	
281	M123701	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8-10)	NOT REVIEWED	
282	M120872	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)	AGREE WITH REVIEWING PATHOLOGIST	
283	M120893	9	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 0.25 G/KG
Sex & Species MALE SD RATS

TMT 4

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 0.25 G/KG
Sacrifice CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
284	M120922	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
285	M120946	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	TISSUE NORMAL	
286	M120956	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
287	M120971	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)[ADJACENT TO TOOTH SLIDE 10]	NOT REVIEWED	
288	M120987	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	AGREE WITH REVIEWING PATHOLOGIST	
289	M121006	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10)	NOT REVIEWED	
290	M121034	5	ORAL MUCOSA - LEUKEMIA MYELO, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
290	M121034 Cont'd	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	NOT REVIEWED	
291	M121044	6	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)	NOT REVIEWED	
292	M121060	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9-11)	NOT REVIEWED	
293	M121089	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)	NOT REVIEWED	
			ORAL MUCOSA - ULCER, MODERATE	AGREE	NOT REVIEWED	
294	M121103	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9-11)	NOT REVIEWED	
			ORAL MUCOSA - FIBROSIS, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
295	M121095	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
295	M121095	5	ORAL MUCOSA - DYSPLASIA, MILD	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9-11)	NOT REVIEWED	
			ORAL MUCOSA - ULCER, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA, BUCCAL - FIBROSIS, MODERATE	AGREE	NOT REVIEWED	
296	M121108	9	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	NOT REVIEWED	
			ORAL MUCOSA - FIBROSIS, MODERATE	AGREE	NOT REVIEWED	
297	M121937	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
298	M121967	5	ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	NOT REVIEWED	
299	M121984	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
299	M121984	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	NOT REVIEWED	
300	M120997	5	ORAL MUCOSA - CYST, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ULCER, MODERATE	AGREE	NOT REVIEWED	
				ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10)	NOT REVIEWED	
301	M122016	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)	NOT REVIEWED	
302	M122024	5	ORAL MUCOSA - ULCER, MODERATE	AGREE	NOT REVIEWED	
				ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	NOT REVIEWED	
303	M122039	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
304	M122051	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	0.25 G/KG			Dosage	0.25 G/KG
Sex & Species	MALE	SD RATS	TMT 4	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
304	M122051	5	ORAL MUCOSA - LEUKEMIA MYELO, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 10)	NOT REVIEWED	
305	M122063	6	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 10)	TISSUE NORMAL	
			ORAL MUCOSA - FIBROSIS, MODERATE	AGREE[WITH HYPERKERATOSIS]	TISSUE NORMAL	
306	M122090	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)[ADJACENT TO TOOTH]	TISSUE NORMAL	
307	M122082	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)[ADJACENT TO TOOTH]	NOT REVIEWED	
308	M122108	5	ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	4
Sex & Species	MALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
308	M122108 Cont'd	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	NOT REVIEWED	
309	M122131	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
310	M122901	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
311	M122912	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
312	M122946	0	ORAL MUCOSA - MISSING	AGREE	NOT REVIEWED	
313	M122958	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	NOT PRESENT IN SECTION (11)	TISSUE NORMAL	
314	M122969	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
315	M122980	4	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	NOT PRESENT IN SECTION (8- 10)[SLIDE 11 MISSING]	NOT REVIEWED	
316	M123003	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	0.25 G/KG			Dosage	0.25 G/KG
Sex & Species	MALE	SD RATS	TMT 4	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
316	M123003	5	ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED NOT REVIEWED	
317	M123292	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
318	M123305	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	TISSUE NORMAL	
319	M123312	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
320	M123355	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	2
Sex & Species	MALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
61	M121241	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
62	M121250	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
63	M121288	5	ORAL MUCOSA - DYSPLASIA, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
64	M121323	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
65	M121346	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
66	M122179	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
67	M122217	5	ORAL MUCOSA - DYSPLASIA, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)	NOT REVIEWED	
68	M122232	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
69	M122271	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	1.0 G/KG			TMT	2
Sex & Species	MALE	SD RATS		Dosage	1.0 G/KG
				Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
70	M122276	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
71	M121371	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)	TISSUE NORMAL	
72	M121398	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
73	M121424	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
74	M121435	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)	NOT REVIEWED	
75	M122104	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
76	M122306	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
77	M123030	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
78	M123064	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 1.0 G/KG
Sex & Species MALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 1.0 G/KG
Sacrifice CHRONIC

TMT 2

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
79	M123086	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
80	M123426	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 11)	TISSUE NORMAL	
81	M123702	6	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
82	M120873	6	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
83	M120894	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
84	M120923	5	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
85	M120947	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
86	M120957	5	ORAL MUCOSA - DYSPLASIA, MARKED	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 11)	NOT REVIEWED	
87	M120972	6				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	2
Sex & Species	MALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
87	M120972	6	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)	NOT REVIEWED	
88	M120988	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	TISSUE NORMAL	
89	M121007	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
90	M121035	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
91	M121045	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
92	M121061	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
93	M121070	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
94	M121082	5	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (9-11)	TISSUE NORMAL	
95	M121096	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	2
Sex & Species	MALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
96	M121109	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
97	M121938	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11, 9)	NOT REVIEWED	
98	M121950	6	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	TISSUE NORMAL	
99	M121985	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
100	M120998	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
101	M121998	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
102	M122025	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11){HYPERKERATOSIS}	AGREE WITH REVIEWING PATHOLOGIST	
103	M122040	5	ORAL MUCOSA - PROLIFERATION, MODERATE	NOT PRESENT IN SECTION (9-11)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	1.0 G/KG			Dosage	1.0 G/KG
Sex & Species	MALE	SD RATS	TMT 2	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
104	M122052	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
105	M122064	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
106	M122091	6	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
107	M122083	5	ORAL MUCOSA - FIBROSIS, MODERATE ORAL MUCOSA - SQUAM CEL CARC, PRESENT	AGREE	AGREE WITH STUDY PATHOLOGIST ORAL MUCOSA: HYPERPLASIA, SQUAMOUS (10, 11)	
108	M122109	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10)[WITH HYPERKERATOSIS]	AGREE WITH REVIEWING PATHOLOGIST	
109	M122114	5	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
110	M122902	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
111	M122913	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	1.0 G/KG			Dosage	1.0 G/KG
Sex & Species	MALE	SD RATS	TMT 2	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
111	M122913	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
112	M122927	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
113	M122939	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
114	M122970	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 10)	AGREE WITH REVIEWING PATHOLOGIST	
115	M122981	5	ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	AGREE	ORAL MUCOSA: HYPERPLASIA, SQUAMOUS (11)	
116	M123004	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
117	M123293	5	ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 9, 11)[HYPERPLASIA WITH INFLAMMATION NEAR TOOTH SLIDE 10]	TISSUE NORMAL	
118	M123306	5				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)			Chemical #	C00117/00117-64
Laboratory	CRC			CAS #	637-92-3
Group	1.0 G/KG			Dosage	1.0 G/KG
Sex & Species	MALE	SD RATS	TMT 2	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
118	M123306	5	ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	TISSUE NORMAL	
119	M123313	5	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	AGREE WITH REVIEWING PATHOLOGIST	
120	M123326	5	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	



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APPENDIX B
SLIDE REVIEW WORK SHEETS
FEMALE

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1001	F121256	7	VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
1002	F121274	7	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
1003	F121306	7	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group VEHICLE CONTROL
Sex & Species FEMALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage VEHICLE CONTROL
Sacrifice CHRONIC

TMT 5

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1003	F121306 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE NOT PRESENT IN SECTION (9, 8, 10-11)[PLANE OF SECTION SLIDE 9, 11]	NOT REVIEWED TISSUE NORMAL	
1004	F121329	7	VAGINA - MISSING UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
1005	F121364	7	ORAL MUCOSA - NORMAL VAGINA - NORMAL	AGREE	NOT REVIEWED	
1006	F122210	10	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL VAGINA - MISSING UTERUS - HISTIO SARC, PRESENT	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED AGREE WITH STUDY PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1006	F122210 Cont'd	10	UTERUS - LEIOMYOSAR, PRESENT ORAL MUCOSA - DYSPLASIA, MODERATE	AGREE NOT PRESENT IN SECTION (9, 8, 10- 11)[PLANE OF SECTION SLIDE 11]	AGREE WITH STUDY PATHOLOGIST AGREE WITH REVIEWING PATHOLOGIST	
1007	F122238	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1008	F122262	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - DYSPLASIA, MODERATE	AGREE AGREE NOT PRESENT IN SECTION (9, 8, 10- 11)[PLANE OF SECTION SLIDE 11]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1009	F122300	7				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1009	F122300	7	VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1010	F123027	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
1011	F121390	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1012	F121414	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1012	F121414 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[FOCAL WITH HYPERKERATOSIS]	NOT REVIEWED TISSUE NORMAL	
1013	F122136	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1014	F122161	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS AND INFLAMMATION]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1015	F122187	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1015	F122187 Cont'd	7	UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1016	F123059	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
1017	F123081	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
1018	F123419	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1018	F123419 Cont'd	8	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1019	F123698	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
1020	F120887	7	VAGINA - INFLAMMATION, MODERATE UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1021	F120906	6	ORAL MUCOSA - NORMAL VAGINA - MISSING UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1021	F120906 Cont'd	6	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1022	F120918	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10- 11)[INFLAMMATION AND FOREIGN MATERIAL SLIDE 10, HYPERKERATOSIS SLIDE 11]	NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
1023	F120935	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, MODERATE ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	AGREE AGREE AGREE NOT PRESENT IN SECTION (8-11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
				ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MODERATE (11)	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1024	F120949	8	VAGINA - MISSING UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1025	F120976	8	VAGINA - NORMAL UTERUS - CARCINOMA, PRESENT ORAL MUCOSA - NORMAL	AGREE NOT PRESENT IN SECTION (23) AGREE	NOT REVIEWED TISSUE NORMAL NOT REVIEWED	
1026	F120984	8	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1027	F121015	7	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1027	F121015 Cont'd	7	UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1028	F121027	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1029	F121039	7	VAGINA - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1030	F121057	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1030	F121057 Cont'd	8	UTERUS, ENDOMETRIUM - METAPL, SQUAMOUS, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10-11)[INFLAMMATION SLIDE 10]	TISSUE NORMAL	
1031	F121077	7	VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10-11)[]	NOT REVIEWED	
1032	F121093	7	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1033	F121934	7				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1033	F121934	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1034	F121956	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - METAPL, SQUAMOUS, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1035	F121964	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1035	F121964 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1036	F121978	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, MODERATE	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1037	F120992	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	NO SECTION PRESENT (22)	NOT REVIEWED	
1038	F121994	7	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1038	F121994 Cont'd	7	UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[]	NOT REVIEWED NOT REVIEWED	
1039	F122008	6	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	MISSING SLIDE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1040	F122019	7	VAGINA - NORMAL UTERUS - HYPERPLASIA, GLANDULAR, MODERATE UTERUS - METAPL, SQUAMOUS, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1041	F122036	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1041	F122036 Cont'd	7	UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1042	F122059	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - NORMAL	AGREE UTERUS - POLYP STROMAL (23)	NOT REVIEWED NOT REVIEWED	
1043	F122079	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1044	F122098	8	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1044	F122098 Cont'd	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1045	F122121	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
1046	F122896	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
1047	F122909	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1047	F122909 Cont'd	8	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1048	F122925	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
1049	F122948	10	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
1050	F122962	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1051	F122985	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1051	F122985	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1052	F122997	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
1053	F123007	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1054	F123296	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1054	F123296 Cont'd	8	UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
1055	F123317	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1056	F123332	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
1057	F123353	7	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (8-11)[WITH HYPERKERATOSIS, OVERLYING INFLAMED SALIVARY SLIDE 11]	TISSUE NORMAL	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	VEHICLE CONTROL	Dosage	VEHICLE CONTROL
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1057	F123353 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MARKED	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 8-10)[INFLAMMATION SLIDE 8 AND 10, HYPERKERATOSIS SLIDE 11]	NOT REVIEWED	
1058	F123375	8	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
1059	F123390	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
1060	F123609	7	UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - MISSING	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group VEHICLE CONTROL
Sex & Species FEMALE SD RATS

TMT 5

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage VEHICLE CONTROL
Sacrifice CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1060	F123609 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
201	F121234	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
202	F121262	8	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, MODERATE	NOT PRESENT IN SECTION (9, 8, 10-11)[PLANE OF SECTION SLIDE 9-10]	NOT REVIEWED	
203	F121285	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 8, 10-11)[SLIDES BROKEN]	NOT REVIEWED	
204	F121317	14				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
204	F121317	14	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - LEIOMYOSAR, PRESENT	UTERUS - SCHWANNOMA MALIGNANT (23)	AGREE WITH REVIEWING PATHOLOGIST	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
205	F121358	9	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8- 11)[PLANE OF SECTION, HYPERKERATOSIS SLIDE 10-11]	NOT REVIEWED	
206	F122199	8	VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MODERATE (11)[HYPERKERATOSIS SLIDE 11]	AGREE WITH REVIEWING PATHOLOGIST	
207	F122226	7				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
207	F122226	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8-11)[PLANE OF SECTION SLIDE 10-11]	NOT REVIEWED	
208	F122250	8	VAGINA - MISSING	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
209	F122274	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
			UTERUS, CERVIX - FIBROSIS, DIFFUSE, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
209	F122274 Cont'd	8	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8- 11)[PLANE OF SECTION SLIDE 10-11]	NOT REVIEWED	
210	F123017	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - AMYLOID DEP, MODERATE ORAL MUCOSA - DYSPLASIA, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
211	F121377	8	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - METAPL, SQUAMOUS, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
212	F121400	7		AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
212	F121400	7	VAGINA - MISSING UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
213	F121431	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
214	F122150	7	VAGINA - MISSING UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
214	F122150 Cont'd	7	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE <Inserted Finding>	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[]	NOT REVIEWED TONGUE: HYPERPLASIA, SQUAMOUS (13, 13)	
215	F122175	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10-11)[]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
216	F123053	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, MODERATE	MISSING SLIDE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MODERATE (11)[]	NOT REVIEWED NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
217	F123070	8	VAGINA - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
217	F123070 Cont'd	8	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
218	F123406	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
219	F123687	9	ORAL MUCOSA - NORMAL VAGINA - MISSING UTERUS - DYSPLASIA, MODERATE UTERUS - INFLAMMATION, CHRONIC, MODERATE UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE AGREE AGREE AGREE	NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST NOT REVIEWED NOT REVIEWED NOT REVIEWED	
220	F120871	12				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
220	F120871	12	VAGINA - NORMAL UTERUS - SCHWANNOMA MAL, PRESENT ORAL MUCOSA - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE NOT PRESENT IN SECTION (8-11)[INFLAMMATION SLIDE 10]	NOT REVIEWED NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
221	F120900	7	VAGINA - NORMAL UTERUS - FIBROSIS, MODERATE UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (8-11)[ON SLIDE 11]	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
222	F120912	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
222	F120912 Cont'd	7	UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
223	F120920	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
224	F120937	10	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 8- 10)[OVERLYING INFLAMMATION SLIDE 11]	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (9, 11)	NOT REVIEWED	
225	F120951	7	ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
225	F120951 Cont'd	7	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8- 10)[OVERLYING AREA OF INFLAMMATION SLIDE 11]	NOT REVIEWED	
226	F120978	7	VAGINA - MISSING UTERUS - POLYP STROMAL, PRESENT UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
227	F121002	8	ORAL MUCOSA - NORMAL VAGINA - NORMAL UTERUS - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
228	F121017	8	ORAL MUCOSA - NORMAL VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
228	F121017 Cont'd	8	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 8-9, 11)[HYPERPLASIA IN AREA OF INFLAMMATION AND FOREIGN MATERIAL SLIDE 10]	NOT REVIEWED NOT REVIEWED	
229	F121029	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
230	F121051	13	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - DYSPLASIA, MODERATE ORAL MUCOSA - INFLAMMATION, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[HYPERKERATOSIS SLIDE 11]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
231	F121065	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	NO SECTION PRESENT (22) AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
232	F121079	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE NOT PRESENT IN SECTION (23)	NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
233	F121105	13	VAGINA - NORMAL UTERUS - SCHWANNOMA MAL, PRESENT ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (9, 11, 8, 10)[OVERLYING AREA OF INFLAMMATION]	NOT REVIEWED AGREE WITH STUDY PATHOLOGIST NOT REVIEWED	
234	F121944	11				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
234	F121944	11	VAGINA - NORMAL UTERUS - SCHWANNOMA MAL, PRESENT ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE <Inserted Finding>	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10-11, 8-9)	NOT REVIEWED AGREE WITH STUDY PATHOLOGIST NOT REVIEWED TONGUE: NORMAL (13, 13)	
235	F121958	8	VAGINA - MISSING UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
236	F121968	8	VAGINA - MISSING UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
237	F121991	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
237	F121991 Cont'd	7	UTERUS - NORMAL ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)	NOT REVIEWED TISSUE NORMAL	
238	F120994	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - METAPL, SQUAMOUS, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
239	F121996	6	ORAL MUCOSA - NORMAL VAGINA - MISSING UTERUS - MISSING ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8-10)	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
240	F122010	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
240	F122010 Cont'd	7	UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 9-10)	NOT REVIEWED NOT REVIEWED	
241	F122021	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 9-10)	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
242	F122046	7	VAGINA - NORMAL UTERUS - DYSPLASIA, SQUAMOUS, MODERATE	AGREE UTERUS - FIBROSIS, SQUAMOUS, MARKED (23)	NOT REVIEWED NOT REVIEWED	
243	F122061	11	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE VAGINA - NORMAL UTERUS - LEIOMYOSAR, PRESENT	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10) AGREE UTERUS - SCHWANNOMA MALIGNANT (23)	NOT REVIEWED NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
243	F122061 Cont'd	11	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10)	TISSUE NORMAL	
244	F122081	6	VAGINA - MISSING UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
245	F122105	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
246	F122123	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
246	F122123 Cont'd	8	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MODERATE (11, 8-10)	AGREE WITH REVIEWING PATHOLOGIST	
247	F122898	9	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - CARCINOMA, PRESENT	AGREE	AGREE WITH STUDY PATHOLOGIST	
			UTERUS - INFLAMMATION, MODERATE	UTERUS - POLYP STROMAL (23)	AGREE WITH REVIEWING PATHOLOGIST	
248	F122911	12	ORAL MUCOSA - NORMAL	AGREE	AGREE WITH STUDY PATHOLOGIST	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - SCHWANNOMA MAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10)[HYPERKERATOSIS SLIDE 11]	AGREE WITH STUDY PATHOLOGIST TISSUE NORMAL	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
249	F122964	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8-10)	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
250	F122950	8	VAGINA - SCHWANNOMA MAL, PRESENT UTERUS - SQUAM CEL CARC, PRESENT <Inserted Finding> ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE UTERUS - METAPLASIA, SQUAMOUS, MODERATE (23) ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (8-11)	NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST UTERUS: POLYP STROMAL (23) NOT REVIEWED	
251	F122973	9	VAGINA - INFLAMMATION, MODERATE UTERUS - HYPERPLASIA, GLANDULAR, MODERATE UTERUS - METAPL, SQUAMOUS, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 0.25 G/KG
Sex & Species FEMALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 0.25 G/KG
Sacrifice CHRONIC

TMT 3

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
251	F122973 Cont'd	9	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
252	F122987	8	VAGINA - INFLAMMATION, MODERATE UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE <Inserted Finding>	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED TISSUE NORMAL TONGUE: HYPERPLASIA, SQUAMOUS (11)	
253	F122999	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
253	F122999 Cont'd	8	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10, 8-9, 11)[INFLAMMATION SLIDE 10]	NOT REVIEWED	
254	F123009	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
			ORAL MUCOSA - INFLAMMATION, MODERATE	NOT PRESENT IN SECTION (8- 11)[UNREMARKABLE]	NOT REVIEWED	
255	F123298	9	VAGINA - NORMAL UTERUS - DYSPLASIA, SQUAMOUS, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE UTERUS - CYST, SQUAMOUS (23) AGREE NOT PRESENT IN SECTION (8)	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
256	F123319	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	0.25 G/KG	TMT	3
Sex & Species	FEMALE SD RATS	Dosage	0.25 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
256	F123319 Cont'd	8	UTERUS - SCHWANNOMA MAL, PRESENT ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11, 10)[INFLAMMATION SLIDE 10]	UTERUS: METAPL, SQUAMOUS (23) NOT REVIEWED	
257	F123334	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (9, 11)[HYPERKERATOSIS SLIDE 11]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
258	F123355	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
259	F123377	2	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 0.25 G/KG
Sex & Species FEMALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 0.25 G/KG
Sacrifice CHRONIC

TMT 3

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
259	F123377 Cont'd	2	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - MISSING	AGREE	NOT REVIEWED	
260	F123392	8	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
				ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8-10)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
1	F121223	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)	NOT REVIEWED	
2	F121261	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 11)	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8-11)	NOT REVIEWED	
3	F121284	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
4	F121316	8				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
4	F121316	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - LEIOMYOMA, PRESENT	AGREE	AGREE WITH STUDY PATHOLOGIST	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	AGREE WITH STUDY PATHOLOGIST	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9-11)	TISSUE NORMAL	
5	F121349	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
6	F122198	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
6	F122198 Cont'd	7	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
7	F122225	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 11)[HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
8	F122249	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MILD	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
9	F122273	7	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE VAGINA - NORMAL UTERUS - NORMAL	NOT PRESENT IN SECTION (8-11) AGREE AGREE	AGREE WITH REVIEWING PATHOLOGIST NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
9	F122273 Cont'd	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
10	F123016	7	VAGINA - MISSING UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
11	F121376	8	ORAL MUCOSA - NORMAL VAGINA - NORMAL UTERUS - SCHWANNOMA MAL, PRESENT <Inserted Finding>	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11) NOT PRESENT IN SECTION (22)	NOT REVIEWED AGREE WITH STUDY PATHOLOGIST	
12	F121399	7	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE VAGINA - NORMAL UTERUS - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11) AGREE AGREE	UTERUS: POLYP STROMAL (23) NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 1.0 G/KG
Sex & Species FEMALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 1.0 G/KG
Sacrifice CHRONIC

TMT 1

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
12	F121399 Cont'd	7	ORAL MUCOSA - DYSPLASIA, MARKED	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9- 10)[PLANE OF SECTION SLIDE 11]	NOT REVIEWED	
13	F121430	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
14	F122149	8	ORAL MUCOSA - NORMAL VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, CERVIX - METAPL, SQUAMOUS, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	1
Sex & Species	FEMALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
14	F122149 Cont'd	8	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
15	F122174	7	VAGINA - NORMAL UTERUS, CERVIX - DYSPLASIA, SQUAMOUS, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE UTERUS, CERVIX - METAPLASIA, SQUAMOUS, MODERATE (23)	NOT REVIEWED NOT REVIEWED	
16	F123052	6	ORAL MUCOSA - NORMAL VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE ORAL MUCOSA - PROLIFERATION, MODERATE	AGREE AGREE NOT PRESENT IN SECTION (8-11) ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11) NOT PRESENT IN SECTION (8-11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
17	F123069	16	VAGINA - NORMAL	NOT PRESENT IN SECTION (22)	NOT REVIEWED	
			UTERUS - SCHWANNOMA MAL, PRESENT	AGREE	AGREE WITH STUDY PATHOLOGIST	
			ORAL MUCOSA - ATROPHY, MARKED	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
18	F123405	8	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS - DYSPLASIA, GLANDULAR, MODERATE	NOT PRESENT IN SECTION (23)	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
19	F123686	8	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
20	F120870	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[WITH HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
21	F120899	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
22	F120907	8	VAGINA - NORMAL UTERUS - LEIOMYOMA, PRESENT UTERUS - POLYP STROMAL, PRESENT ORAL MUCOSA - NORMAL	AGREE AGREE AGREE AGREE	NOT REVIEWED AGREE WITH STUDY PATHOLOGIST AGREE WITH STUDY PATHOLOGIST NOT REVIEWED	
23	F120919	9				

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	1
Sex & Species	FEMALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
23	F120919	9	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8-11)	TISSUE NORMAL	
24	F120936	9	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - METAPL, SQUAMOUS, MODERATE	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
25	F120950	8	VAGINA - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	1
Sex & Species	FEMALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
25	F120950 Cont'd	8	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
26	F120977	10	VAGINA - NORMAL UTERUS - DYSPLASIA, SQUAMOUS, MODERATE UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE UTERUS - METAPLASIA, SQUAMOUS, MARKED (23) AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
27	F121001	11	VAGINA - NORMAL UTERUS - INFLAMMATION, MODERATE UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE AGREE	TISSUE NORMAL NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
27	F121001 Cont'd	11	ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	NOT PRESENT IN SECTION (8-11)	NOT REVIEWED	
28	F121016	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 8-10)	NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
29	F121028	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (9, 11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
30	F121040	7	VAGINA - NORMAL UTERUS - NORMAL	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
30	F121040 Cont'd	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
31	F121058	9	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - DEGEN, CYSTIC, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
32	F121078	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
33	F121104	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
33	F121104 Cont'd	8	ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (10-11)[WITH INFLAMMATION SLIDE 10]	NOT REVIEWED	
34	F121935	8	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (8-10)[WITH INFLAMMATION SLIDE 8-10]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
35	F121957	9	VAGINA - NORMAL UTERUS - METAPL, SQUAMOUS, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
36	F121965	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	1
Sex & Species	FEMALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
36	F121965 Cont'd	8	UTERUS - FIBROSIS, DIFFUSE, MODERATE ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
37	F121979	7	VAGINA - INFLAMMATION, MODERATE UTERUS - NORMAL ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE ORAL MUCOSA - FIBROSIS, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
38	F120993	7	<Inserted Finding> VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE		AGREE WITH REVIEWING PATHOLOGIST AGREE WITH STUDY PATHOLOGIST TONGUE: NORMAL (13)	
39	F121995	7		AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (10-11)[WITH HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE) **Chemical #** C00117/00117-64
Laboratory CRC **CAS #** 637-92-3
Group 1.0 G/KG **TMT** 1 **Dosage** 1.0 G/KG
Sex & Species FEMALE SD RATS **Sacrifice** CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
39	F121995	7	VAGINA - NORMAL UTERUS - NORMAL ORAL MUCOSA - NORMAL <Inserted Finding>	AGREE AGREE AGREE[HYPERKERATOSIS SLIDE 11]	NOT REVIEWED NOT REVIEWED NOT REVIEWED TONGUE: NORMAL (13)	
40	F122009	8	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT UTERUS, CERVIX - ATROPHY, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED NOT REVIEWED	
41	F122020	6	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
41	F122020 Cont'd	6	ORAL MUCOSA - SQ CL PAPILLOM, PRESENT	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)	TISSUE NORMAL	
42	F122045	8	VAGINA - NORMAL UTERUS - FIBROSIS, DIFFUSE, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
43	F122060	8	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE UTERUS - LEIOMYOMA (23) ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)[WITH HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
44	F122080	14	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
44	F122080 Cont'd	14	UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - SQUAM CEL CARC, PRESENT	AGREE	ORAL MUCOSA: HYPERPLASIA, ATYPICAL (10, 11, 11R)	
45	F122104	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS, ENDOMETRIUM - HYPERPLASIA, MODERATE	AGREE	NOT REVIEWED	
			ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MINIMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[HYPERKERATOSIS]	NOT REVIEWED	
46	F122122	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
47	F122897	7	VAGINA - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT	1
Sex & Species	FEMALE SD RATS	Dosage	1.0 G/KG
		Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
47	F122897 Cont'd	7	UTERUS - NORMAL ORAL MUCOSA - ATROPHY, MODERATE	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
48	F122910	6	VAGINA - INFLAMMATION, MODERATE UTERUS - POLYP STROMAL, PRESENT UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
				UTERUS, CERVIX - GRANULAR CELL TUMOR BENIGN (23)	NOT REVIEWED	
49	F122926	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - ATROPHY, MODERATE VAGINA - NORMAL UTERUS - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE)
Laboratory CRC
Group 1.0 G/KG
Sex & Species FEMALE SD RATS

Chemical # C00117/00117-64
CAS # 637-92-3
Dosage 1.0 G/KG
Sacrifice CHRONIC

TMT 1

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
49	F122926 Cont'd	7	ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MARKED	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	AGREE WITH REVIEWING PATHOLOGIST	
50	F122949	7	VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - NORMAL	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	
51	F122972	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE	AGREE	NOT REVIEWED	
52	F122986	7	ORAL MUCOSA - NORMAL VAGINA - NORMAL UTERUS, CERVIX - INFLAMMATION, MODERATE	AGREE AGREE AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
52	F122986 Cont'd	7	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11, 9-10)[HYPERKERATOSIS SLIDE 11]	NOT REVIEWED NOT REVIEWED	
53	F122998	7	VAGINA - NORMAL UTERUS - POLYP STROMAL, PRESENT	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
54	F123008	8	ORAL MUCOSA - ATROPHY, MODERATE VAGINA - NORMAL	AGREE	NOT REVIEWED	
55	F123297	8	UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE VAGINA - NORMAL	AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11) AGREE	NOT REVIEWED NOT REVIEWED NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ETHYL-TERT-BUTYL-ETHER (ETBE) **Chemical #** C00117/00117-64
Laboratory CRC **CAS #** 637-92-3
Group 1.0 G/KG **TMT** 1 **Dosage** 1.0 G/KG
Sex & Species FEMALE SD RATS **Sacrifice** CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
55	F123297 Cont'd	8	UTERUS - NORMAL	AGREE	NOT REVIEWED	
			ORAL MUCOSA - NORMAL	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
56	F123318	8	VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - NORMAL	AGREE	NOT REVIEWED	
57	F123333	7	ORAL MUCOSA - NORMAL	AGREE	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
58	F123354	8	UTERUS - POLYP STROMAL, PRESENT	AGREE	NOT REVIEWED	
			ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MINIMAL (11)	NOT REVIEWED	
			VAGINA - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - METAPL, SQUAMOUS, MODERATE	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title	ETHYL-TERT-BUTYL-ETHER (ETBE)	Chemical #	C00117/00117-64
Laboratory	CRC	CAS #	637-92-3
Group	1.0 G/KG	TMT 1	Dosage 1.0 G/KG
Sex & Species	FEMALE SD RATS	Sacrifice	CHRONIC

CID Number	Histology Number	No Of Slides	Study Pathologist's Diagnoses	Reviewing Pathologist's Comments	PWG Coordinator's Comments PWG Consensus	Action To Be Taken <i>blank = No Change Required</i>
58	F123354 Cont'd	8	ORAL MUCOSA - ATROPHY, MODERATE	AGREE	NOT REVIEWED	
59	F123376	7	VAGINA - NORMAL UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - DYSPLASIA, SQUAMOUS, MODERATE	NOT PRESENT IN SECTION (22) AGREE ORAL MUCOSA - HYPERPLASIA, SQUAMOUS, MILD (11)[HYPERKERATOSIS]	NOT REVIEWED NOT REVIEWED TISSUE NORMAL	
60	F123391	7	VAGINA - INFLAMMATION, MODERATE UTERUS - POLYP STROMAL, PRESENT UTERUS, ENDOMETRIUM - INFLAMMATION, MODERATE ORAL MUCOSA - PROLIFERATION, DIFFUSE, MODERATE	AGREE AGREE AGREE NOT PRESENT IN SECTION (9-11)	NOT REVIEWED NOT REVIEWED NOT REVIEWED TISSUE NORMAL	



Experimental Pathology Laboratories, Inc.

APPENDIX C

PWG PARTICIPANTS CURRICULA VITAE

Charles B. Clifford, D.V.M., Ph.D.

email charles.clifford@crl.com

Present Position

Director, Pathology and Technical Services, Charles River

Education

1974	B.S. (Zoology)	Michigan State University
1977	D.V.M.	Michigan State University
1981-1983	Pathology Residency	Walter Reed Army Institute of Research
1988	Ph.D. (Pathology) minors in Immunology and Cell Biology	Cornell University

Professional and Scientific Societies

American College of Veterinary Pathologists (Diplomate, by examination)	1983 - present
Society of Toxicologic Pathologists (Full Member)	1989 - present
American Veterinary Medical Association	1981 - present
American Association of Laboratory Animal Science	1992 - present

Experience

- 1977-1978 Veterinary Officer, Veterinary Detachment, Bayonne, NJ. Supervised approximately 30 civilian and military personnel who inspected most subsistence shipped to the U.S. military in Europe. Conducted sanitary inspection of 5 commissaries and over 80 civilian food processors and suppliers in New York City, Long Island and northern New Jersey. Responsible for zoonosis control at 4 Army posts.
- 1978 Assistant Officer-in-Charge, Team D, 106th Medical Detachment, Pusan, Republic of Korea. Supervised inspection of all subsistence shipped to the U.S. Army in Korea, and managed the only two military veterinary clinics within a 90 mile radius.
- 1978-1979 Officer-in-Charge, Team A, 106th Medical Detachment, Oujongbu, Republic of Korea. Supervised all food inspection for U.S. troops stationed north of Seoul, including along the DMZ, public health consultation for the 2nd Infantry Division. Also was Assistant Chief and Surgeon for the U.S. Army veterinary clinic in Seoul.
- 1979-1980 Course Director, US Army Animal Care Specialist School, Washington, DC, the only school in the U.S. Army to train Animal Health Technicians. Was responsible for course content and administration, counseling and supervision of 5 faculty members, and 120 students per year. Taught courses in pathology, anesthesia, radiology, and the Cardiovascular, Respiratory and Gastrointestinal System.
- 1980-1983 Pathology Resident, Division of Pathology, Walter Reed Army Institute of Research. Provided collaborative histopathology support to the institute, including studies of renal toxicity, pulmonary trauma and toxicity using rodent, lagomorph, canine, and primate models. Served as diagnostic pathologist for the Institute's rodent and primate colonies. Completed all requirements for the board examination of the American College of Veterinary Pathologists.
- 1982-1984 Assistant Senior Army Social Aide to the President of the United States for White House functions, such as receptions and State dinners.
- 1983-1984 Staff Pathologist, Division of Pathology, Walter Reed Army Institute of Research. Developed a rat model and conducted independent research on pathogenesis and healing of pulmonary lesions due to concussive pressure waves. Collaborated in studies of hemorrhagic shock, military systems hazards assessment, and toxicopathology of anti-schistosomal drugs. Assisted in training of 3 pathology residents per year in preparation of the veterinary pathology board examination.
- 1984-1987 Research Assistant (doctoral student), Cornell University. Conducted original research on the ontogeny of neutrophil function and the inflammatory response, comparing fetuses, neonates, and adults. Designed a novel model of *in utero* pulmonary inflammation in the sheep, permitting repetitive blood sampling and bronchoalveolar lavage. Initiated and developed a histopathology training series for

3 veterinary pathology residents from non-English speaking countries. Each resident then successfully completed the veterinary pathology board examination. Completed all requirements for Doctor of Philosophy degree.

- 1987-1991 Research Pathologist and Assistant Chief of Pathology, Letterman Army Institute of Research. Supervised the Institute's postmortem and clinical pathology laboratories. Conducted original research in distribution and toxicity of purified modified hemoglobin solutions. Collaborated with other scientists in model design and pathology support of Good Laboratory Practices Act-compliant toxicity studies (principal pathologist), pathogenesis of neurovascular trauma, hemorrhagic shock and perfusion injury, wound healing, and pre-clinical testing of candidate resuscitative fluids. Served on a rotating duty as diagnostic pathologist for animal postmortem examinations. Member of the Institute's Animal Care and Use Committee.
- 1991-2001 Staff Officer, US Army Medical Research and Materiel Command. Two weeks annual duty as a senior staff member in office with budget and program oversight of all Army biomedical research concerning biological and chemical agents, >\$100 million/annum. Duties included technical review of research proposals, analysis and synopsis of diverse research projects for senior pentagon management. Retired as Colonel.
- 1991-1993 Senior Pathologist, Charles River Laboratories. Oversee all aspects of pathology support of the world's largest supplier of laboratory animals, with approximately \$600 million in annual sales and production facilities in the U.S. and more than 10 other countries. Collaborate in the definition of new animal models, including genetically engineered animals. Supervise extramural development of new diagnostic technologies. Design and conduct pathology service protocols in support of biotechnology and pharmaceutical customers. Address and resolve customer concerns regarding unexpected research findings or other pathology-related issues. Key professional for CRL swine xenotransplantation efforts.
- 1993-present Director, Pathology and Technical Services. (*additional duties to above*) Supervise two other pathologists and the Charles River Technical Assistance Department, which provides information to customers concerning normative data, test procedures, husbandry, health, and all other matters relating to laboratory animals. Oversee corporate toxicology consultant, preparation of technical and reference papers on Historical Control Data..
- 2001-2003 (additional duties) Direct responsibility for Contract Research Services department, approximately \$2 million annual revenue. Specialty areas include oncology, vaccine testing, novel imaging studies.

Licensure

Michigan, #5124, 1977 to present.

Inventions

Hairless Immunodeficient Mouse Model (U.S. application no. 12/047,948)

PUBLICATIONS

1. Clifford, C.B., Jaeger, J.J., Moe J.B., and Hess, J.L., Gastrointestinal Lesions in Lambs Due to Multiple Low-Level Blast Over-Pressure Exposure. Military Medicine, 149:491-495, 1984.
2. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and Clifford, C.B., Increased Adhesiveness of Complement-Stimulated Calf Neutrophils and Its Pharmacologic Inhibition. Journal of Leukocyte Biology, 41:465-473, 1987.
3. Boswell, G.D., Brooks, D.E., Murray, A.J., Doye, A.A., Disselhorst, D.J. Chin, C.L., and Clifford, C.B., Exogenous Methemoglobin as a Cyanide Antidote in Rats. Pharmaceutical Research, 5:749-752, 1988.
4. Clifford, C.B., Slauson, D.O., Neilsen, N.R., Suyemoto, M.M., Zwahlen, R.D., and Schlafer, D.H., Ontogeny of Inflammatory Responsiveness: Superoxide Anion Generation by Phorbol Ester-Stimulated Fetal, Neonatal, and Adult Bovine Neutrophils. Inflammation, 13:221-231, 1989.
5. Clifford, C.B., Wessels, D.W., and Smith, C.D., Morphologic effects of hypervolemic administration DBBF hemoglobin in the rat, Biomaterials, Art. Cells, Art. Organs, 18:321-328, 1990.
6. Schuschereba, S.T., Clifford, C.B., Vargas, J.A., Bunch, D., and Bowman, P.D., Morphologic alteration in rat retina after hypervolemic infusion of cross-linked hemoglobin, Biomaterials, Art. Cells, Art. Organs, 18:299-307, 1990.
7. Sondeen, J.L., Gonzaludo, G.A., Loveday, J.A., Deshon, G.E., Clifford, C.B., Hunt, M.M., Rodkey, W.G., and Wade, C.E., Renal Responses to Graded Hemorrhage in Conscious Pigs. Am J Physiol, 259:R119-R125, 1990.
8. Yuan, X-Q, Wade C.E., and Clifford, C.B., Traumatic Brain Injury Suppresses Spontaneous Hemodynamic Recover from Hemorrhagic Shock in Rats, J. Neurosurg. 75:408-414, 1991.

9. Yuan, X-Q, Wade C.E., and **Clifford, C.B.**, Immediate hypertensive response to fluid percussion brain injury may be related to intracerebral hemorrhage and hypothalamic damage. *J.Neurotrauma*, 8:219-228, 1991.
10. Dubick, M.A., Pfeiffer, J.W., **Clifford, C.B.**, Runyon, D.E., Kramer, G.C., Comparison of Intraosseous and Intravenous Delivery of Hypertonic Saline/Dextran in Anesthetized, Euvolemic Pigs, *Annals of Emergency Medicine*, 21:498-503, 1992.
11. Pascual, J.M.S., Runyon, D.E., Watson, J.C., **Clifford, C.B.**, Dubick, M.A., Kramer, G.C., Resuscitation of hypovolemia in pigs using near saturated sodium chloride solution in dextran, *Circulatory Shock*, 40:115-124, 1993.
12. Runyon, D., Bruttig, S, Dubick, M., **Clifford, C.**, Kramer, G., Resuscitation from hypovolemia in swine with intraosseous infusion of a saturated salt-dextran solution, *Journal of Trauma* 36:11-19, 1994.
13. **Clifford, C.B.**, Walton, B.J., Reed, T.H., Coyle, M.B., White, W.J., and Amyx, H.L., Hyperkeratosis in nude mice caused by a coryneform bacterium: Microbiology, transmission, clinical signs, and pathology, *Laboratory Animal Science*, 45:131-139, 1995.
14. Moore, D.H., **Clifford, C.B.**, Crawford, I.T., Cole, G.M., and Baggett, J.M., Review of nerve agent inhibitors and reactivators of acetylcholinesterase, in Enzymes of the Cholinesterase Family, edited by Quinn, D.M., *et al.*, pp. 297-304, Plenum Press, New York 1995.
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16. Vargas, K.J., Stephens, C., **Clifford, C.B.**, Gray, K.N., and Price, R.E. Dystrophic cardiac calcinosis in C3H/HeN mice. *Laboratory Animal Science*, 46:572-575, 1996.
17. Loeb, W.F., Das, S.R., Harbour, L.S., Turturro, A., Bucci, T.J., and **Clifford, C.B.**, Clinical biochemistry, in Pathobiology of the Aging Mouse, Vol. 1, edited by Mohr, U., *et al.*, pp. 3-20, ILSI Press, Washington, D.C., 1996
18. Evans, M.G., Cartwright, M.E., Sahota, P.S., and **Clifford, C.B.**, Proliferative lesions of the skin and adnexa in rats. In: **Guides for Toxicologic Pathology**. STP/ARP/AFIP, Washington DC., 1997
19. **Clifford, C.B.**, and White, W.J., The guinea pig, in The Clinical Chemistry of Laboratory Animals, 2nd edition, edited by Loeb, W.F. and Quimby, F.W., pp.65-70, Taylor & Francis, Philadelphia, P.A., 1999.
20. Gaillard, E.T., and **Clifford, C.B.**, Common Diseases, in The Laboratory Rat, edited by Krinke, G.J., pp. 99-132, Academic Press, San Diego, 2000.

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23. Kohn, D.F., and **Clifford, C.B.**, Biology and Diseases of Rats, in Laboratory Animal Medicine, edited by Fox, J.G., et. al., Academic Press, San Diego, 2002
24. Bemis, D.B., Shek, W.R., and **Clifford, C.B.**, *Bordetella bronchiseptica* infection of Rats and Mice. Comparative Medicine, 53(1):11-20, 2003
25. Shek WR, Pritchett KR, **Clifford CB**, White WJ, Large-scale rodent production methods make vendor barrier rooms unlikely to have persistent low-prevalence parvoviral infections. Contemp Top Lab Anim Sci 44(4):37-42, 2005
26. Rohde CM, Wells DF, Robosky LC, Manning ML, **Clifford CB**, Reily MD, Robertson DG Metabonomic evaluation of Schaedler altered microflora rats. Chem Res Toxicol 20(10):1388-92, 2007
27. **Clifford, CB**, and Watson, J. Old enemies, still with us after all these years. ILAR Journal, 49(3):291-302, 2008
28. Pritchett-Corning, KR, Cosentino, J, and **Clifford, CB**, Prevalence of infectious agents in laboratory mice and rats, Laboratory Animals, 43:165–173, 2009
29. Albers, TM, Simon, MA and **Clifford, CB**, Histopathology of Naturally Transmitted "Rat Respiratory Virus": Progression of Lesions and Proposed Diagnostic Criteria, Veterinary Pathology, 46:992-999, 2009.
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TECHNICAL REPORTS

1. Frost, D.F., Hall, R.D., Zaucha, G.M., Waring, P.P., **Clifford, C.B.**, Wheeler, C.R. and Korte, D.W., Twenty-eight Day Subchronic Toxicity Study of Physostigmine Salicylate in Beagle Dogs. Institute Report #310, Letterman Army Institute of Research, U.S. Army, October 1988.
2. Frost, D.F., Omaye, S.T., Zaucha, G.M., **Clifford, C.B.**, Wheeler, C.R., Schuschereba, S.T., and Korte, D.W., Twenty-eight Day Subcutaneous Subchronic Toxicity Study of Physostigmine Salicylate in Rats. Institute Report #317, Letterman Army Institute of Research, U.S. Army, November 1988.
3. Frost, D.M., Zaucha, G.M., Omaye, S.T., **Clifford, C.B.**, and Korte, D.W., Acute Intravenous Toxicity of Hypertonic Saline/Dextran 70 and its Constituents in Beagle Dogs. Institute Report #392, June 1989.
4. Zaucha, G.M., Frost, D.F., Omaye, S.T., **Clifford, C.B.**, and Korte, D.W., Fourteen-Day Subacute Intravenous Toxicity Study of Hypertonic Saline/Dextran 70 and its Constituents in Beagle Dogs. Institute Report #404, Letterman Army Institute of Research, November 1989.
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7. Morgan, E.W., Zaucha, G.M., Waring, P.P., LeTellier, Y., Seewald, J.B., **Clifford, C.B.**, and Korte, D.W., Ninety Day Subchronic Oral Toxicity Study of Pyridostigmine Bromide in Rats. Institute Report #435, Letterman Army Institute of Research, May 1990.
8. Morgan, E.W., Zaucha, G.M., Waring, P.P., LeTellier, Y., Seewald, J.B., **Clifford, C.B.**, and Korte, D.W., One Hundred Eighty Day Subchronic Oral Toxicity Study of Pyridostigmine Bromide in Rats. Institute Report #441, Letterman Army Institute of Research, June 1990.

ABSTRACTS

1. Slauson, D.O., Skrabalak, D.S., Zwahlen, R.D., Neilsen, N.R. and **Clifford, C.B.**, Equine Neutrophil Aggregation and Adhesiveness Responses to C5a and AGEPC. Joint Conference of the International Leukocyte Culture conference and the Reticuloendothelial Society, 1985.
2. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and **Clifford, C.B.**, Adhesiveness Responses of Neonatal Neutrophils to Zymosan-Activated Plasma. Joint Conference of the International Leukocyte Culture Conference and the Reticuloendothelia Society, 1985.
3. **Clifford, C.B.**, Slauson, D.O., Zwahlen, R.D., Schlafer, D.H., and Neilsen, N.R., Superoxide Anion Generation by Bovine Neutrophils: A Comparison of Fetal, Neonatal, and Adult Cells. American College of Veterinary Pathologists Annual Meeting, December, 1985.
4. Zwahlen, R.D., Slauson, D.O., Neilsen, N.R., and **Clifford, C.B.**, Adhesiveness of C5a-Treated Bovine Neonatal Neutrophils: Influence of Anti-Inflammatory Agents. American College of Veterinary Pathologists Annual Meeting, December 1985.
5. Slauson, D.O., Zwahlen, R.D., Neilsen, N.R., and **Clifford, C.B.**, Aggregation and Adhesiveness Responses of Equine Neutrophils to C5a and Platelet Activating Factor. American College of Veterinary Pathologists Annual Meeting, December 1985.
6. Slauson, D.O., Zwahlen, R.D., Neilsen, N.R., **Clifford, C.B.**, Bochsler, P.N., and Enright, F.M., Pharmacologic Inhibition of C5a-induced Increased Adhesiveness of Newborn and Adult Neutrophils by Steroidal and Non-Steroidal Anti-Inflammatory Drugs. American College of Veterinary Pathologists Annual Meeting, December 1986.
7. Miller, R.E., Lightner, L., **Clifford, C.B.**, Reid, W.A., Jones, D., and Witter, K.R., The Efficacy of Topically Applied Niclosamide at Preventing Schistomiasis mansoni in Rhesus Monkeys. American Society of Tropical Medicine and Health Annual Meeting, 1988.
8. Loveday, J.A., Gonzaludo, G.A., Sondeen, J.L., Rodkey, W.G., **Clifford, C.B.**, Deshon, G.E., Wade, C.E., Surgical Preparation for the Study of Renal Function in Conscious Swine. Presented at American Association for Laboratory Animal Science Annual Meeting, 1989.
9. **Clifford, C.B.**, Wessels, D.W., and Smith, C.D., Morphologic Effects of HBXLA99 in Rats, Biomaterials, Art. Cells, Art. Organs, 17:680, 1989.
10. Schuschereba, S.T., **Clifford, C.B.**, and Vargas, J.A., Effects of Hypervolemic Infusion of Cross-Linked Hemoglobin (DBBF-Hb) on the Rat Retina, Biomaterials, Art. Cells, Art. Organs, 17:698, 1989.

11. Korte, D.W., Frost, D.F., Zaucha, G.M., Waring, P.P., **Clifford, C.B.**, and Wheeler, C.R., 28-day Toxicity in Beagle Dogs of Physostigmine Salicylate Administered via Subcutaneously Implanted Alzet Osmotic Minipumps, Proc. West. Pharmacol. Soc., 32:159, 1989.
12. Dubick, M.A., Runyon, D.E., **Clifford, C.B.**, and Kramer, G.C., Comparison of Intraosseous with IV Infusions of Hypertonic Saline Dextran-70, Ann. Emerg. Med., 20:480, 1991.
13. Runyon, D.E., **Clifford, C.B.**, Bruttig, S.P., Wade, C.E., Dubick, M.A., and Kramer, G.C., Resuscitation of Hypovolemia Using Intraosseous Infusion of a Small Volume of 25% NaCl/24% Dextran-70, Ann. Emerg. Med., 20:480, 1991.
14. Bowman, P.D., **Clifford, C.B.**, McFaul, S.J., Tacha, D., and Johnson, T.W., Distribution of Purified Hemoglobin in Mouse Tissue as a Function of Time after Administration: An Immunocytochemical Study. FASEB, 1991.
15. **Clifford, C.B.**, Gianni, F.J., and White, W.J., *Pneumocystis carinii* and modern methods of rodent breeding and husbandry. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
16. Henderson, K.S., **Clifford, C.B.**, and Dionne, J.A., Comparison of the polymerase chain reaction with histological technique for detection of *Pneumocystis carinii*. Joint meeting of Am Soc Parasitologists and Soc Protozoologists, 1996.
17. Kim, N.M., Bailey, L., Olson, T., **Clifford, C.B.**, Benso, F.J., Sgrulloni, S.J., Duenas, E., Cleland, J.L., Putney, S.D., and Riley, M.G.I., Immunogenicity evaluation of ProLease® hGH: A sustained release formulation. Society of Toxicology, 1997.
18. Albers, T.M. and **Clifford, C.B.** Eosinophilic granulomatous pneumonia: A strain-related lesion of high prevalence in the Brown Norway rat, Contemporary Topics, 39(4):61-62, 2000
19. Albers, T. M. and **Clifford, C. B.** Transmission of rat respiratory virus in a rat colony: Gross and histopathological progression of lesions. Contemp Top. Lab Anim Sci 42[4], 73-74. 2003.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

DHHS/CFSAN/FDA/ OFAS/ Senior Science and Policy Staff /Pathology
5100 Paint Branch Parkway HFS-205
College Park MD 20740
(301) 436-1308

EDUCATION:

Ph.D., The Ohio State University, Columbus, OH, USA
Applied Veterinary Pathology Residency, The Ohio State University, Columbus, OH, USA
Dr. Vet. Med., Justus-Liebig University, Giessen, Germany
D.V.M., Justus-Liebig University, Giessen, Germany

PROFESSIONAL ORGANIZATIONS AND MEMBERSHIPS:

Recognized Fellow of the International Academy of Toxicologic Pathology (IATP; 2010 - present)
European Society of Toxicologic Pathology (ESTP; 2009 – present)
US Society of Toxicologic Pathology (STP; 1998 - present)
American College of Toxicology (ACT; 1999 - present)
Association of Government Toxicologists (AGT; 2000- present) – President Elect (2009-11)
Charles Louis Davis D.V.M. Foundation for the Advancement of Veterinary and Comparative Pathology (2000 – present)

United States and Canadian Academy of Pathology, Inc. (USCAP 2000-2010)
American Association for the Advancement of Science (AAAS 1992-2010)
National Society for Histotechnology (NSH 2004-2009)

PROFESSIONAL EXPERIENCE:

CURRENT DUTIES:

Expert Toxicologic Veterinary Regulatory Review Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

4/10 – present

The incumbent in the Office of Food Additive Safety (OFAS) in CFSAN is recognized by FDA as subject matter expert for Toxicologic Veterinary Regulatory Review Pathology (Veterinary Officer / Pathologist) and serves as an authoritative expert in her field, conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs independent histo-pathological slide evaluations and serves as authoritative expert in regulatory toxicologic veterinary pathology on Center-, Inter Agency-, and national / international professional committees and provides a regulatory perspective when serving on Pathology Working Groups (PWGs) convened to resolve complex pathology issues.

Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Senior Toxicologic Veterinary Pathologist, Senior Science and Policy Staff / Pathology
Department of Health and Human Services / FDA / CFSAN / OFAS /College Park, MD.

2/2007- 3/10. The incumbent serves in the Office of Food Additive Safety (OFAS) in CFSAN as Toxicologic Veterinary Pathologist (Veterinary Officer / Pathologist) conducting independent, in-depth regulatory reviews and complex safety evaluations of pathology data from regulatory submissions from all FDA Centers. The incumbent performs a wide range of administrative functions pertaining to the budget process, property management and pathology contract management.

Supervisor: Dennis Keefe, Ph.D., (Director, SSPS, OFAS, CFSAN/FDA)

Acting Branch Chief, Pathology Branch

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

1/2005-2/2007 Center-wide Reorganization. The incumbent is an experienced regulatory reviewer and applies in-depth professional knowledge and skills as Veterinary Medical Officer / Pathologist conducting independent safety evaluations of pathology data from regulatory petitions for the Division of General Scientific Support (DGSS).

The incumbent manages independently the Pathology Branch and the associated histopathology laboratory, performing a wide range of administrative functions pertaining to daily operations (such as the budget process, property management and contract management). The Pathology Branch and the Pathology Laboratory provide a full range of pathology support functions

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PROFESSIONAL EXPERIENCE (contd.):

for requesting Offices/researchers such as pathology protocol design, monitoring animal-study in-life-phases, performing necropsies, guiding the tissue processing, evaluating histological glass slides and reporting of pathology data. The incumbent instructs and trains laboratory associated personnel and adjunct students from the University of Maryland. The incumbent is solely responsible for the development and application of all immuno-histopathological services provided by the Pathology Laboratory.

Supervisor: Prem Dua, D.V.M., Ph.D., (Director, DGSS, OSAS, CFSAN/FDA)

Senior Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2002-12/2004. The incumbent assists the Director of the Division of General Scientific Support (DGSS) with regulatory (food petition) reviews. To do this the incumbent applies knowledge of FDA laws/regulations and extensive experience in pathology data analysis. The incumbent is further involved in administrative matters pertaining to the operation of the Pathology Branch, e.g. the zero based budgeting process. The incumbent's significant research experience involves her extensively as Co-principal investigator in several research projects with Center and/or adjunct scientists from the University of Maryland (UMD). The incumbent serves as student mentor and instructor to laboratory personnel and UMD/JIFSAN students, and promotes the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Staff Toxicologic Pathologist

Department of Health and Human Services / FDA / CFSAN / OSAS / DGSS / Pathology Branch, College Park, MD.

01/2001 – 12/2002. The incumbent provides histo-pathological analysis and support to requesting researchers associated with Governmental Offices (e.g. OARSA) and/or joint facilities such as the University of Maryland (under the umbrella of the Joint Institute for Food Safety and Applied Nutrition (JFSAN)). The incumbent participates as Immuno-pathologist and/or as Co-principal-investigator in protocol design, monitors animal-study in-life-phases, performs necropsies, guides the tissue processing, evaluates histological slides and conducts the final pathology-relevant reporting of assigned animal research studies. The incumbent initiates the development of immuno-histopathological services provided by the Pathology Laboratory.

Supervisors: Fred Hines, D.V.M., (Pathology Branch Chief), Prem Dua D.V.M., Ph.D., (DGSS Director)

Toxicologic Pathologist, Novartis Pharmaceuticals Inc. East Hanover, NJ.

11/98 –11/2000. The incumbent generates and evaluates pathology data of assigned acute, subacute and chronic preclinical drug-safety studies which also entailed partial, direct/indirect supervision of technical personnel assigned to these studies. The incumbent is assigned to projects with standard design and/or those requiring an appropriate level of interpretive experience and knowledge. A current knowledge of recent advances and new equipment/procedures is important to achieve optimum results. At the conclusion of each study, the incumbent participates in the data review/analyses to determine target organ toxicity. The incumbent participates in the study design and in the evaluation and implementation of new procedures to improve preclinical drug-safety operations. The incumbent is a member of scientific boards, project teams, and advisory committees and performs other duties as assigned by upper management.

Supervisor: Dr. Pritam Sahota, D.V.M, Ph.D.

Veterinary Research Pathologist, Pathology Associates International (PAI), Immunology and Molecular Pathology Division Frederick, MD 21701

09/1996 – 98. The incumbent evaluates designs and interprets studies assessing the cross-reactivity characteristics of monoclonal antibodies in human and animal tissues (in vivo/in vitro exposure), the localization of monoclonal antibodies by means of immuno-labeling techniques and conducts development and application of molecular and cellular histopathologic technology to characterize and resolve mechanistic problems associated with biopharmaceutical product development.

Supervisor: Bill Hall, V.M.D., Ph.D.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PROFESSIONAL EXPERIENCE (contd.):

Graduate Research Associate (Ph.D. / Veterinary Pathologist), The Ohio State University, Department of Veterinary Biosciences, Columbus, Ohio

1992-1996 Research conducted evaluates anti-retroviral drug-effects (mainly AZT) on cellular immune responses and immune-cell precursor frequencies. Effector-cell frequency analysis, by limiting dilution analysis (LDA), allows not only qualitative assessment but also quantitation of the effects noted. Two animal models, an outbred feline model for retroviral infection and an inbred mouse model for allograft rejection are utilized in these studies. Research activities: Histopathology, immunology, retro-virology, in-vivo and in-vitro drug testing, immunohistochemistry, vaccine development, cell culture and molecular biology.

Thesis advisor: Lawrence E. Mathes, Ph.D., Professor.

Graduate Teaching Associate and Resident (Veterinary Pathologist / Ph.D.)

1990-1992 (continued services during Ph.D training until 1996) The Ohio State University
Department of Veterinary Biosciences
Columbus, Ohio

Graduate Assistant (Dr.med.Vet.)

1988-1990 Justus-Liebig University
Giessen, Germany

Research performed to obtain a "Dr. Vet. Med." degree centers on the immunohistologic characterization of the cellular immune response to bacterial infection with *Coxiella burnetii* in a murine model. Results illustrated that cellular mechanisms are crucially involved in the pathogenesis of chronic infection with *C. burnetii*.

Thesis advisor: Dr. Wolfgang Baumgaertner, D.V.M., Ph.D., Professor.

Graduation from Veterinary School (DVM)

1988 Justus-Liebig University
Giessen, Germany

LEADERSHIP EXPERIENCE:

- Elected board member to IATP 2011: Vice president 2011-13; President 2013-15
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA recognized (Agency Peer Review) Expert for Toxicologic Veterinary Regulatory Review Pathology (April 2011)
- President Elect of the Association of Government Toxicologists (AGT term 2010-2011)
- Councilor to the Board of the Association of Government Toxicologists (AGT), 2006 & 2008
- CFSAN Immunotox Redbook working group: chair
- STP SRPC Regulatory Liaison since 2005 till present
 - Hepatic Enzyme Induction working group liaison since 2007/ chair – Dec 2008-10
 - Historical Control Data working group SRPC liaison, 2006-2009
- Pathology Laboratory Chief, and Acting Pathology Branch Chief; providing training, instructions and guidance to Laboratory Technicians and visiting scientists from UMD, regarding duties and functions of the Pathology Branch and its Laboratory.
- Mentor to JIFSAN students; Mentor to UMD and Pathology Laboratory students.
- Histopathology mentor and instructor for Laboratory Biologist: training included pathology terminology, histology, histopathology, tissue trimming, tissue processing, preparation of paraffin blocks, microtoming, H&E staining of routine slides, Immunohistochemical staining, archiving, laboratory administrative work and reagent ordering.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

SERVICES AND RESPONSIBILITIES:

- Regulatory liaison to the Scientific Regulatory and Policy Committee (SRPC) of the Society of Toxicologic Pathology (STP) since 2005
 - SRPC liaison to the Historical Control Data working group; 2006 -09 - Best Practice manuscript published TP 2009; 37(5) 679-93.
 - SRPC liaison to the Hepatic Enzyme Induction Risk Assessment (HEI- RA) working group since 2007; chair since Dec. 2008 – 2010.
 - SRPC liaison to the Joint Regulatory Affairs Committee (JRAC) between STP and the American College of Veterinary Pathology (ACVP); since 2006 - 2009.
 - Invited Member of the STP Regulatory Forum editorial group for the Journal of Toxicologic Pathology since 2007 – ongoing.
- CFSAN Immunotox Redbook committee since 2006
 - Chair: Dec 07 – ongoing.
- Association of Government Toxicologists (AGT)
 - Board member councilor 2005-07; elected for–second term 2008; President elect 2009-10; President 2010-11; Past President 2011-12 – 3 year leadership commitment - ongoing.
- Acting Chief of the Pathology Branch and Laboratory / DGSS (1/2005- until CFSAN reorganization 2/2007).
- CFSAN Cancer Assessment Committee (CAC) Member – Pathologist – since 2004.
- CFSAN Pathology Services and Archiving Contract Project Officer since 2006 – recertified as COTR July 31, 2009.
- Property Management Officer 2005-07.
- CFSAN Science Council Committee Member since 2004.
 - SC Scientific Dissent Resolution policy draft subcommittee 2007-09.
 - SC membership charter following the CFSAN 2007 reorganization subcommittee Scientific Achievement Award-subcommittee (2004, '05, '06, '07, '08).
 - Manuscript clearance subcommittee 2004.
- CFSAN Toxicology Redbook Committee Member since 2003.
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) steering Committee Member 2002-'07. And JIFSAN Grant – Pathology Support Collaborator to the University of Maryland (UMD), Department of Food Science.

AWARDS / Professional Recognitions

- Recognized FDA Expert for Toxicologic Veterinary Regulatory Review Pathology through Agency peer review March 2010.
- Recognized as Fellow IATP (International Academy of Toxicologic Pathology) 2009.
- FDA / CFSAN Outstanding Customer Service Award, Office of Food Additive Safety for *pathology support to CDRH on the histopathological evaluation of mouse tissues for the distribution of nano-material*, June 2008.
- FDA and Center-level Crosscutting Award that includes CFSAN Employees, FDA Melamine Award, Adulterated protein investigations, analysis, planning, scientific review and emergency response team for *exemplary performance to protect the public health from adulterated protein through actions of investigations, sample analyses, method development, assignment, planning, emergency response, scientific review and risk assessment*, June 2008.
- FDA / CFSAN Honor Award: Aspartame Carcinogenicity Review Team, Office of Food Additive Safety for *exceptional performance in evaluating the results of a number of carcinogenicity studies on aspartame, including the high-profile European Ramazzini Foundation study*, June 2008.
- FDA Outstanding Service Award for *outstanding performance while participating on an expert pathology review panel in response to an Inter-Center pathology support request from CDER* June 2007.
- FDA Outstanding Service Award for *outstanding performance in the regulatory review of pathology issues and in providing critical pathology support to the Office of Food Additive Safety* June 2006.
- FDA Outstanding Service Award for *sustained superior performance in evaluating and resolving complex regulatory pathology review issues as well as supporting collaborating scientists* June 2005.
- FDA Outstanding Service Award for *sustained superior performance in the evaluation of substantial and voluminous regulatory and experimental pathology data* June 2004.
- Team Award as member of the OARSA Food Allergenicity Team for *outstanding team effort in successfully completing pilot studies to evaluate a unique animal model for the study of human food allergenicity* June 2003.
- FDA Outstanding Service Award for *sustained superior performance in the Pathology Branch instituting a food-allergy rat model, leveraging with the UMD and establishing a IH laboratory* June 2003

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- Quality Performance Award for *developing methods to quantify "altered crypt foci" in the colon of rats* July 2002
- Quality Performance Award for *Pathology support services with the University of Maryland (UMD)* June 2002

PUBLICATIONS AND PRESENTATIONS:

Technical Reports: lists on - regulatory review projects (upon request)
 - regulatory research projects (upon request).

Poster / Journal presentations and Talks:

Boorman G., Wolf D., Francke-Carroll S., and Maronpot R. Guest Editorial: Pathology Peer Review. Tox Path 38:1009-1010, 2010.

Botts S., Ennulat D., Francke-Carroll S., Graham M., Maronpot R., and Mohutsky M. Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 796-798, 2010.

Mohutsky M., Romeike A., Meador V., Lee W., Fowler J. and Francke-Carroll S. (Chair) Introduction to Hepatic Drug Metabolizing Enzyme induction in Drug Safety Evaluation Studies. Tox Path 38: 799-809, 2010.

Griffis L., Twerdok L.E., Francke-Carroll S., Biles R., Schroeder R., Bolte H., Hall W., Faust H. and Rojko J. Comparative 90-day dietary study of paraffin wax in Fischer-344 and Sprague-Dawley rats. Food and Chemical Toxicology: 2010, 48: 363-372.

Patri A., Umbreit T., Zeng J., Nagashima K., Goering P., Francke-Carroll S., Golden E., Weaver J., Miller T., Sadrieh N., McNeil S., and Stratmeyer M. Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution after intravenous and subcutaneous injection in mice. Journal of Applied Toxicology 2009, 29: 667-672.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Pletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Potential for a Global Historical Control Database for Proliferative Rodent Lesions. Tox Path 2009; 37(5) 677-8.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin, Peddada, S., R., Pletcher J., Rinke M., Schmidt S., Taylor I. and Wolf D. Regulatory Forum: Best Practices for Use of Historical Control Data of Proliferative Rodent Lesions. Tox Path 2009; 37(5) 679-93.

Kerlin R., Hutto D., Silverman L., Francke-Carroll S., Vahle J. Regulatory forum for Toxicologic Pathology: an update. Toxicologic Pathology 2008; 36(5):760.

Austin C., Umbreit T., Brown K., Barber D., Dair B., Francke-Carroll S., Feswick A., Saint-Louis M., Hikawa H., and Goering P. Distribution of iv-injected silver nanoparticles in pregnant mice and developing embryos. Poster presentation at the Society of Toxicology's 48th annual meeting held in Baltimore MD, March 15-19, 2009.

Invited Talk: Francke-Carroll S., Society of Toxicologic Pathology (STP), 27th annual meeting: As Module of the Effective Communication for the Toxicologic Pathologist - Career Development Courses: "Communicating Pathology Information Effectively to Regulatory Agencies". San Francisco, CA June 20-26, 2008.

Keenan C., Elmore S., Francke-Carroll S., Kemp R., Kerlin R., Pletcher J., Rinke M., Schmidt S., Taylor I., Wolf D. STP Working Group on Historical Control Data of Proliferative Rodent Lesions. Presented at the 26th annual meeting of the Society of Toxicologic Pathology (STP) in San Juan, Rio Mar, Puerto Rico, June 2007.

Umbreit T.H., Goering P.L., Miller T.J., Weaver J.L., Francke-Carroll S., Sadrieh N., Kauffman J., Guthrie J., Robertson J., Stratmeyer M.E.: *Toxicity and Tissue Distribution of Titanium Dioxide (TiO₂) Nanoparticles in subcutaneous and intravenously injected mice over 6 months* Poster presentation at the Society of Toxicology's 47th annual meeting held in Seattle, WA, March 21-26, 2008.

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

PUBLICATIONS AND PRESENTATIONS (contd.)

Daly K., Tracy A., Francke-Carroll S., Wang T., Malik M. and Magnuson B.A. Enhanced estrogenic responses and sensitivity to azoxymethane following dietary soy isoflavone supplementation in older female rats. *Food Chem Toxicol* 2007 Apr; 45 (4):628-37.

Umbreit T., Goering P., Francke-Carroll S., Patri A., McNeil S., Weaver J., Miller T., Sadrieh N., and Stratmeyer M. *Energy dispersive X-ray analysis of titanium dioxide nanoparticle distribution in mice*. Poster presentation at the Society of Toxicology's 46th annual meeting held in Charlotte, NC March 25-29, 2007.

Yoon DM, Hawkins EC, Francke-Carroll S., Fisher JP. Effect of construct properties on encapsulated chondrocyte expression of insulin-like growth factor-1. *Biomaterials* 2007 Jan 28 (2); 299-306.

Morton D, Kemp RK, Francke-Carroll S., Jensen K, McCartney J, Monticello TM, Perry R, Pulido O, Roome N, Schafer K, Sellers R, Snyder PW. Best practice for reporting pathology interpretations within GLP toxicology studies. *Tox Path* 2006; 34 (6); 806-9.

Su Y., Yu T., Lala G., Francke-Carroll S., and Magnuson B.A. Protection of side effects of 5-flurouracil by anthocyanin-rich extracts. International Research Conference on Food and Nutrition and Cancer, Washington DC, July 2005. Published in *J. Nutr.* 135.12S:3054.

Ferri, M, Francke-Carroll S. and Magnuson B.A. JIFSAN Student project: Development of immuno-histochemical staining techniques for PCNA and APOPTOSIS tissue markers on rat tissues in the CFSAN Pathology Laboratory. Poster presentation at the 11th Annual FDA Science Forum, 2005, Washington Convention Center, Washington DC.

Hinton D.M., Lorenzo M., Harper S.B. and Francke-Carroll S., (2004). USFDA, CFSAN, Laurel, MD. Progress in the evaluation of an in-bred rat strain ("asthmatic rat") for predicting the allergic potential of food and other Proteins. Seminar presented at OFAS/CFSAN/USFDA Vermont Ave May 6, 2004.

Hinton D.M., Lorenzo M.E., Harper S.B., Francke-Carroll S., O'Neill R.K., Chirtel S.J., Calvo M.S. An In-Bred Rat Strain (the FDA "Asthmatic Rat") for Predicting the Allergic Potential of Proteins and for Evaluating the Efficacy of Drugs and Dietary Supplements in Respiratory (Asthmatic) and Cardiovascular Studies Poster presentation (Board Number B-08) at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Magnuson B., Daly K., Malik M., Wang T., Francke-Carroll S.. Enhanced Sensitivity of Female Rats to Azoxymethane following Dietary Soy Isoflavone Supplementation. Poster presentation at the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age-related liver pathology increases azoxymethane toxicity in F344 female rats in an aging study on colon cancer chemoprevention with dietary soy. Website publication (Board Number D-PO-01) for the 10th Annual FDA Science Forum, 2004, Washington Convention Center, Washington DC.

Francke-Carroll S., Daly K., Wang T. and Magnuson B.A. Underlying age related liver pathology increases Azoxymethane toxicity in F344 female rats in an aging study on colon cancer and nutrition. Poster presentation # 500 at the Society of Toxicology's 43rd annual meeting held in Baltimore, MD, March 21-26, 2004.

Hinton D.M., Lorenzo M., Harper S.B. and Francke-Carroll S., (2004). USFDA, CFSAN, Laurel, MD. Progress in the evaluation of an in-bred rat strain ("asthmatic rat") for predicting the allergic potential of food and other Proteins. , *The Toxicologist* (Platform Session on Hypersensitivity, Abstract #662, 43rd Annual Meeting of the Society of Toxicology).

Hinton D.M., Myers M.J., Raybourne R.A., Francke-Carroll S., Sotomayor R.E., Shaddock J., Warbritton A., Chou M.W.: Immunotoxicity of Aflatoxin B₁ in Rats: Effects on Lymphocytes and the Inflammatory Response in a Chronic Intermittent Dosing Study. *Toxicological Sciences*; 73, 362-377, 2003.

Curriculum Vitae

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PUBLICATIONS AND PRESENTATIONS (contd.)

Humphreys S.H., Dua P., Francke-Carroll S., Bolger P.M., Calamus: Reassessment of Carcinogenicity. *Toxicological Sciences* 66, 1-S, 268, 2002.

Francke S., Orosz C.G., Hsu J, and Mathes L.E.: Immunomodulatory Effect of Zidovudine (ZDV) on Cytotoxic T Lymphocytes Previously Exposed to ZDV. *Antimicrob Agents Chemother* Sept; 46 (9): 2865-71, 2002.

Francke-Carroll, S., Montgomery J.E., Hines F.A., and Magnuson B.A.: The Effect of a Dietary Curcumin Supplement on the Development of Histopathological Age-associated Changes in Male Azoxymethane-Treated F344 Rats. Presented at the twenty-first Annual Symposium of the Society of Toxicologic Pathology, Denver, CO, June. 2-6, 2002.

Francke S., Orosz C.G., Hayes K.A. and Mathes L.E.: Effect of Zidovudine on the primary cytolytic T-lymphocyte response and T-cell effector function. *Antimicrob Agents Chemother* Jul; 44(7): 1900-5, 2000.

Hayes K.A, Phipps A, Francke S. and Mathes L.E.: Antiviral therapy reduces viral burden but does not prevent thymic involution in young cats infected with feline immunodeficiency virus. *Antimicrob Agents Chemother* Sep; 44(9): 2399-2405, 2000.

Mathes L.E., Hayes K.A., Francke S. and Phipps A.: Comparison of pathogenesis of the Mount Airy strain of feline immunodeficiency virus (FIV-MD) in pediatric and adult cats. Presented at the Third International Feline Retrovirus Research Symposium, Ft. Collins, CO, March 6-9, 1998.

Francke S. Evaluation of the Immunomodulatory effects of the anti-retroviral drug Zidovudine (AZT). Presented in partial fulfillment of the requirements for the degree Doctor of Philosophy in the Graduate School of The Ohio State University. The Ohio State University, Columbus, OH, USA, 1996.

Francke, S., Hayes K.A., Orosz C.G., and Mathes L.E.: Frequency Analysis of the Immunosuppressive effect of Zidovudine (AZT) on murine lymphocyte function in vitro by Limiting Dilution Analysis (LDA). Presented at the forty-seventh Annual Meeting of The American College of Veterinary Pathologists, Seattle, WA, Dec. 2-6, 1996.

Hayes, K.A., Francke S., Phipps A and Mathes L.E.: AZT therapy in adult cats chronically infected with FIV-MD. Presented at the Third International Feline Retrovirus Research Symposium, Ft. Collins, Co., March 5-9, 1996.

Francke S. and Capen C.C.: Undifferentiated carcinoma in the anterior mediastinum of a dog. Presented at the Eastern North American Veterinary Diagnostic Pathology Conference, Cobleskill, NY, Oct. 21-22, 1995.

Hayes K.A., Wilkinson J.G., Frick R., Francke S. and Mathes L.E.: Early suppression of viremia by ZDV does not alter the spread of feline immunodeficiency virus infection in cats. *J Acqu Immune Syndr & Hum Retrovir* 9:114-22, 1995.

Francke, S. Histological and immunohistological evaluation of the spleen in Balb/cJ (H-2^d) mice following infection with *Coxiella burnetii*. (*Histologische und immunohistologische Untersuchung der Milz von Balb/cJ (H-2^d)-Maeusen nach Infektion mit Coxiella burnetii*): Inaugural - Dissertation, Veterinary Medicine, Justus-Liebig-University, Giessen, Germany, 1991.

PETER GREAVES MBChB FRCPath

Dr Greaves is a medical graduate trained in laboratory medicine, specialising in human and experimental histopathology and toxicology. He has over twenty-five years experience in human and experimental pathology as well as toxicology, pre-clinical drug safety evaluation and drug development. He advises both pharmaceutical companies and government in these areas.

PROFESSIONAL HISTORY:

CONSULTING PATHOLOGIST

March 2005 – present:

Advises on preclinical drug safety evaluation and toxicological pathology. Engaged in research in toxicological pathology, carcinogenesis and cancer chemoprevention. Member of the Committee on Carcinogenicity, United Kingdom

MEDICAL RESEARCH COUNCIL TOXICOLOGY UNIT, LEICESTER

March 2000 – February 2005: Senior Research Scientist & Head of Pathology.

Responsibility for the histopathological study of disease models and adverse hepatic effects of drugs in obesity in combination with genetic analysis, laser capture dissection microscopy, in situ hybridisation and immunocytochemistry.

ASTRAZENECA (FORMERLY ZENECA, ICI PHARMACEUTICALS), ALDERLEY PARK, CHESHIRE

March 1990 - February 2000: Head of Safety of Medicines Group

Responsibility for all preclinical safety studies and kinetics and metabolism work with approximately 300 staff in the UK and US in support of the discovery and development of novel drugs for all of ex-ZENECA Pharmaceuticals.

ZENECA (FORMERLY ICI) PHARMACEUTICALS, ALDERLEY PARK, CHESHIRE

January 1989 - February 1990: Head of Pathology

Responsibility for a group of 80 staff conducting histopathological evaluation of toxicity studies.

PARKE-DAVIS RESEARCH INSTITUTE, MISSISSAUGA, ONTARIO, CANADA

January 1987 - December 1988: Director of Research Institute

Responsibility for the Sheridan Park Research Laboratory (60 staff) undertaking preclinical safety studies for Parke-Davis Research centred at Ann Arbor, Michigan.

WELLCOME RESEARCH LABORATORIES, BECKENHAM, KENT, ENGLAND

January 1985 - December 1986: Head of Toxicology and Metabolism

Responsibility for drug safety evaluation, preclinical drug kinetics and radiochemistry at the Beckenham site (50 staff), in collaboration with Experimental Pathology and Toxicology at Research Triangle Park site.

CENTRE DE RECHERCHE, LABORATOIRES PFIZER, AMBOISE, FRANCE

September 1981 - December 1984: Director of Pathology

April 1979 - August 1981 - Pathologist

**WESTMINSTER HOSPITAL MEDICAL SCHOOL & ST STEPHEN'S HOSPITAL,
LONDON**

**September 1976 - March 1979 - Senior Registrar in Histopathology
February 1975 - February 1976 - Registrar in Histopathology**

**MEDIZINISCHE HOCHSCHULE, HANNOVER, GERMANY.
February 1976 - September 1976 - Assistant in Pathology**

**NEWCASTLE GENERAL HOSPITAL, NEWCASTLE-UPON-TYNE
September 1972 - February 1975 - Senior House Officer in Pathology**

**GRAVESEND HOSPITAL, KENT
October 1972 - May 1972 - House Physician**

**CHICHESTER HOSPITAL, WEST SUSSEX
February 1971 - August 1971 - House Surgeon**

EDUCATION AND DEGREES:

- * MBChB University of Birmingham, England, 1969
- * MRCPath in human histopathology, Royal College of Pathologists, London, 1977
- * FRCPath in histopathology & toxicology, Royal College of Pathologists, London, 1989
- * GMC Registration in Morbid Anatomy and Histopathology under the European Specialist Medical Qualifications order 1995 (number 1491454)
- * Medical Defence Union membership (membership number 095078D)

OTHER ACTIVITIES:

- * Member of the *Committee on Carcinogenicity*, United Kingdom 2008-present
- * Member of *International Life Sciences Institute (ILSI) – Europe* project on data selection for modelling of substances that are genotoxic and carcinogenic 2009-2011
- * Chairman of *International Harmonization of Nomenclature and Diagnostic Criteria* committee for rodent soft tissue pathology 2009-present
- * Member of the *Veterinary Products Committee* of the United Kingdom 2003-2007
- * Member of the editorial board for *Toxicologic Pathology* 2002-2006
- * Member of the editorial board for *Experimental & Toxicologic Pathology* 2000-2007.
- * Chairman of *Zeneca Leisure* 1996-1999: This group managed all the company leisure activities, clubs and leisure facilities, turnover £1 million per annum
- * Member of Personnel steering group for *Zeneca R&D* in the UK 1996-1999
- * Member of Health & Safety Steering Committee for the Alderley Park R&D site 1996-1999
- * Biological Safety Officer, MRC Toxicology Unit 2000-2003

Date: 21 July 2010

PUBLICATIONS:

Books:

Greaves P. and Faccini J.M. (1992): Rat Histopathology: A Glossary for Use in Toxicity and Carcinogenicity Studies, *2nd edition*. Elsevier, Amsterdam.

Greaves P. (2007): Histopathology of Preclinical Toxicity Studies: Interpretation and Relevance in Drug Safety Evaluation. Elsevier, Amsterdam. *3rd edition*.

Main scientific papers:

Greaves P., Filipe M.I. and Branfoot A.C. (1980): Transitional mucosa and survival in human colorectal cancer. *Cancer*, **46**, 764-770.

Greaves P. and Faccini J.M. (1981): Fibrous histiocytic neoplasms spontaneously arising in rats. *Br.J.Cancer*, **43**, 402-411.

Greaves P., Martin J. and Masson M-T. (1982): Spontaneous rat malignant tumors of fibrohistiocytic origin. An ultrastructural study. *Vet.Pathol.*, **19**, 497-505.

Greaves P and Rabémampianina Y. (1982): Choice of rat strain: A comparison of the general pathology and tumour incidence in 2-year old Sprague-Dawley and Long-Evans rats. In: New Toxicology for Old, *Arch.Toxicol.*, Suppl 5, 298-303.

Villanove F. and Greaves P. (1983): Sialoglycoconjugates in normal and neoplastic rat liver: A histochemical study. *Pathol.Res.Pract.*, **178**, 171.

Michel M.C., Greaves P., Martin J. and Greaves P. (1983): Etude ultrastructurale des lymphomes malins non Hodgekiniens gastrointestinaux spontanés chez le hamster Syrien (*Mesocricetus auratus*). *Biol.Cell.*, **48**, 10a.

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Higgins A.J., Faccini J.M and Greaves P. (1985): Coronary hyperemia and cardiac hypertrophy following inhibition of fatty acid oxidation. Evidence of a regulatory role for cytosolic phosphorylation potential. In: N.S. Dhalla and D.J. Hearse (Eds), *Advances in Myocardiology*, Vol. 6, pp. 329-338, Plenum.

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- Spencer A. and Greaves P. (1987): Polyarteritis in a beagle dog colony. *J.Comp.Pathol.*, **97**, 122-128.
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Parrott, E., Butterworth, M., Green, A., White I.N.H. and Greaves P. (2001): Adenomyosis - a result of disordered stromal differentiation. *Am.J.Pathol.*, **159**, 623-630.

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Green, A.R., Edwards, R.E., Greaves, P. and White, I.N.H. (2003): Comparison of the effect of oestradiol, tamoxifen and raloxifene on nerve growth factor alpha expression in specific neonatal mouse uterine cell types using laser capture microdissection. *Journal of Molecular Endocrinology* **30**, 1-11.

Jones, H.B., Macpherson, A., Siddall, R., Betton, G.R., Davis, A.S. and Greaves, P. (2003): Endothelin antagonist-induced coronary and systemic arteritis in the beagle dog. *Toxicol. Pathol.* **31**, 263-272.

Donald, S. Verschoyle, R.D., Greaves, P., Gant, T.W., Colombo, T., Zaffaroni, M., Frapolli, R., Zucchetti, M., D'Incalci, M., Meca D., Riccardi, R., Lopez-Lazaro, L., Jimeno, J. and Gescher, A.J. (2003): Complete protection by high-dose dexamethasone against the hepatotoxicity of the novel antitumor drug Yondelis (ET-743) in the Rat. *Cancer Res.* **63**, 5902-5908.

Damment, S.J.P., Greaves, P. and Downs, N. (2003): The toxicology of lanthanum carbonate, a new non-aluminium, non-calcium phosphate binder. *Journal of the American Society of Nephrology* **14**, 204A

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Green, A.R. Styles, J.A., Parrott, E.L., Gray, D., Edwards, R.E., Smith, A.G., Gant, T.W. Greaves, P., Al-Azzawi, F. and White, I.N.H (2005): Neonatal tamoxifen treatment of mice leads to adenomyosis but not uterine cancer. *Expt. Toxicol. Pathol.* **56**, 255-263.

Davies, R., Schuuman A., Barker, C.R., Clothier B., Chernova, T., Higginson, F.M., Judah, D.J., Dinsdale, D., Edwards, R.E. Greaves, P., Gant, T.W. and Smith A.G. (2005). Hepatic gene expression in protoporphyrin Fech mice is associated with cholestatic injury but not a marked depletion of the heme regulatory pool. *Am.J.Pathol.* **166**, 1041-1053.

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prostate (TRAMP) tissue by ^1H -NMR analysis—evidence for unusual phospholipid metabolism. *Prostate*, **68**, 1035–1047.

Teichert, F., Verschoyle, R.D., Greaves, P., Thorpe, J.F., Mellon, J.K., Steward, W.P., Farmer, P.B., Gescher, A.J. and Singh, R. (2009): Determination of 8-oxo-2-deoxyguanosine and creatinine in murine and human urine by liquid chromatography-tandem mass spectrometry: application to chemoprevention studies. *Rapid Communications in Mass Spectrometry*, **23**, 258–266.

Greaves P. (2009): Pathological techniques in toxicology. In: General and Applied Toxicology, pp 691–706, B. Ballantyne T. Marrs and T. Syversen, (Eds), **3rd Edition**. John Wiley and Sons Ltd., Chichester.

[In Press withheld under Exemptions B4 and B6]



Experimental Pathology Laboratories, Inc.

**JERRY F. HARDISTY
CHIEF EXECUTIVE OFFICER/SENIOR PATHOLOGIST**

EDUCATION:

Iowa State University, Pre-Veterinary, 1965-1967

Iowa State University, D.V.M., 1971

Certified by the American College of Veterinary Pathologists, 1976

Adjunct Associate Professor at the School of Veterinary Medicine,
NC State University, 1983

PRESENT POSITION AND EXPERIENCE:

2010 - Present. Chief Executive Officer/Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the overall implementation of the strategic goals and objectives of EPL. Provide leadership toward the company's philosophy, mission, strategy, and goals and objectives. Direct the company's business development and marketing efforts. Serve as the Principal Investigator as a Study Pathologist, Peer Review Pathologist and Chairperson for Pathology Working Groups and Scientific Advisory Panels.

1998 - 2010. President and Veterinary Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of contract research pathology laboratories in Virginia and North Carolina. The company serves both government and university research and the safety assessment programs of the pharmaceutical, chemical, and cosmetic industries.

1994 - 1998. Vice President, Operations and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for overall management and direction of pathology research laboratories in North Carolina and Virginia.

1978 - 1994. Director and Pathologist, Experimental Pathology Laboratories, Inc., Research Triangle Park, North Carolina

Responsible for the project management, direction and technical supervision of the North Carolina branch of EPL. Responsible for the microscopic evaluation of toxicological studies. Responsible for the National Toxicology Program's Pathology Quality Assessment Program and Operations of the NTP Archives.

1976 - 1978. Pathologist/Project Manager, Experimental Pathology Laboratories, Inc., Herndon, Virginia

Responsible for the management of EPL's Carcinogenesis Support Laboratory. Project Manager of a program to provide Tracor Jitco with Quality Assurance in the NCI Carcinogenesis Testing Program. Technical supervision of a program to provide pathology support services to the Carcinogenesis Program of the National Cancer Institute. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies.



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PRESENT POSITION AND EXPERIENCE – Continued

1972-1976 Research Pathologist, Veterinary Pathology Branch, Biomedical Laboratory, Edgewood Arsenal, Maryland

Dr. Hardisty was a preceptor in the U.S. Army preceptorship program in Veterinary Pathology. During this time he performed gross and microscopic diagnoses of spontaneous disease and changes produced by experimental procedures in laboratory animals. He prepared reports describing and interpreting these experimental results.

During this time he was principal investigator for the reproductive, mutagenic, teratogenic studies performed at the laboratory. This work consisted of revising previous experimental protocols and designing new experimental protocols to be utilized at the laboratory. The experimental design employed required the gross examination of pregnant female rats and fetuses for evidence of fetal toxicity and teratogenesis. He trained biological technicians to perform timed matings in rats, examine serially sectioned fetuses for malformations, and to examine fetal skeletons for prenatal abnormalities.

1971-1972 Attending Veterinarian, Division of BioSensor Research,
Walter Reed Army Institute of Research

Dr. Hardisty studied the radiographic and morphologic lesions of several musculoskeletal diseases of the German Shepherd Dog. In association with Dr. Wayne Riser, he investigated the pathogenesis and possible genetic relationship of canine hip dysplasia, eosinophilic panosteitis and ununited anconeal processes in an attempt to reduce their incidence through a selective breeding program.

PROFESSIONAL MEMBERSHIPS:

Diplomate, American College of Veterinary Pathologists

ACVP Subspecialty in Toxicologic Pathology

American College of Toxicology

Society of Toxicology

Society of Toxicologic Pathologists

British Society of Toxicologic Pathologists

International Academy of Toxicologic Pathology

American Veterinary Medical Association

North Carolina Society of Toxicology

Charles Louis Davis, D.V.M. Foundation

The Society of Phi Zeta

The Society of Gamma Sigma Delta

The Fraternity of Alpha Zeta

The Fraternity of Omega Tau Sigma

American Association for the Advancement of Science

Standardized System of Nomenclature and Diagnostic Criteria (SSNDc), The



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PROFESSIONAL ACTIVITIES – Continued

Society of Toxicologic Pathologists, 1987-1995.
Executive Committee, The Society of Toxicologic Pathologists, 1994- 1998.
Executive Committee Chairman, The Society of Toxicologic Pathologists, 1997-1998.
Joint Committee for STPs/ILSI on International Standardization of
Nomenclature and Diagnostic Criteria for Toxicologic Pathology, 1994-1995,
Co-Chairman 1995-Present.
President-Elect, The Society of Toxicologic Pathologists, 1999-2000.
President, The Society of Toxicologic Pathologists, 2000-2001.
Past President, The Society of Toxicologic Pathologists, 2001-2002.
Long Range Planning Committee, American College of Toxicology, 2002.
North American Director, International Academy of Toxicologic Pathology, 2002.
FDA Clinical Pharmacology Subcommittee of the Advisory Committee for
Pharmaceutical Sciences, FDA Center for Drug Evaluation and Research, 2003.

EDITORIAL REVIEW BOARD:

International Agency for Research on Cancer (WHO), Classification of Rodent Tumors, Part II, The Mouse, 1995-2001.

Editorial Review Board for *Fundamental and Applied Toxicology*, Society of Toxicology Board of Publications, 1996-1998.

Editorial Review Board for *Toxicological Sciences*, Society of Toxicology Board of Publications, 1998-2004.

Editorial Review Board for *Experimental and Toxicologic Pathology*, 2000.

Editorial Board of *Toxicologic Pathology*, 2006-2008.

PUBLICATIONS AND PAPERS:

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid Hormone 1-84 in a 2-Year Study in Fischer 344 Rats. The Society of Toxicologic Pathology

Factors predisposing to urolithiasis in feedlot cattle. Hardisty JF and Dillman RC. The Iowa State University Veterinarian, Iowa State University, Ames, Iowa, 33(2), 77-81, 1971.

Reduction of frequency of hip dysplasia in military dogs. Riser WH, Hardisty JF and Castleberry MW. In Proceedings, Canine Hip Dysplasia Symposium and Workshop, OFA, Columbia, MO. 1972.

Genetic influence of the male on the incidence of canine hip dysplasia. Hardisty JF, Scalera SE., Castleberry MW and Riser WH. In Proceedings, Canine Hip Dysplasia Symposium and Workshop, OFA, Columbia, MO. 1972.



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Evaluation of the effects of chemical compounds on the reproductive system of rats. Hardisty JF. Presented at the Biomedical Laboratory Review and Analysis, April 1975.

Reproductive studies with quint essence compounds. Hardisty JF, Presented at the Biomedical Laboratory Review and Analysis of Quint Essence, January 1976.

Effects of KZ/IP mixture on the reproductive system. Hardisty JF and Pellerin RJ. Edgewood Arsenal Technical Report, 1976.

Reproductive studies with diisopropylmethylphosphate in rats. Hardisty JF, Pellerin RJ, Biskup RF and Manthei JH. Edgewood Arsenal Technical Report ARCSL TR 77037, May 1977.

Quality assurance in pathology. Hardisty JF, Ward JM and Griesemer RA. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Mononuclear cell leukemia in Fischer 344 rats. Hardisty JF. NCI-NCTR Pathology Workshop, Bethesda, MD, June 1978.

Quality assurance for pathology in rodent carcinogenesis tests. Ward JM, Goodman DG, Griesemer RA, Hardisty JF, Schueler RL, Squire RA and Strandberg JD. Journal of Environmental Pathology and Toxicology, 2, 371-378, Nov.-Dec. 1978.

Neoplasms and pigmentation of the thyroid gland in F-344 rats exposed to 2,4-diaminoanisole sulfate, a hair dye component. Ward JM, Stinson, SF, Hardisty JF, Cockrell BY and Hayden DW. Journal of the National Cancer Institute, Vol. 62, No. 4, 1979. Apr;62(4) 1067-73

Renal carcinogenic and nephrotoxic effects of the flame retardant TRIS[(2,3-dibromopropyl) phosphate] in F-344 rats and B6C3F1 mice. Reznik G, Ward JM, Hardisty JF and Russfield A. Journal of the National Cancer Institute, Vol. 63, No. 1, July 1979.

Correlation between gross observations of tumors and neoplasms diagnosed microscopically in carcinogenesis bioassays in rats. Kulwich BA, Hardisty JF, Gilmore CE and Ward JM. Journal of Environmental Pathology and Toxicology, 3, 281-287, December 1979.

Evaluation of procedures suggested for reducing the pathology workload in a carcinogenesis testing program. Hardisty JF, Ward JM, Douglas JF and Fears TR. Journal of Environmental Pathology and Toxicology, 3, 167-176, December 1979.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Presented for the conference to re-evaluate the Toxicology of Vinyl Chloride Monomer, Polyvinyl Chloride and Structural Analogues on March 20-21, 1980, at the National Institute of Health, Bethesda, MD.

Cancer induction following single and multiple exposures to a constant amount of vinyl chloride monomer. Hehir RM, McNamara BP, McLaughlin J, Willigan DA, Bierbower G and Hardisty JF. Environmental Health Perspectives, 41, 63-72, October 1981.

Carcinogenesis bioassay of 2,6-Xylylidine in rats. Hardisty JF, Montgomery CA and Kornreich M. The Toxicologist, Vol 3, No. 1, March 1983.

Chronic toxicity and oncogenicity bioassay of inhaled toluene in Fischer 344 rats. Gibson JE and Hardisty JF. Fundamental and Applied Toxicology, 3: 315-319, 1983.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Quality assurance in pathology for rodent carcinogenicity tests, by GA Boorman, CA Montgomery, JF Hardisty, SL Eustis, MJ Wolfe and EE McConnell. In: Handbook of Carcinogen Testing, (H Milman and E Weisberger, eds), pp. 345-357. New Jersey: Noyes Publications, 1985.

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Factors influencing laboratory animal spontaneous tumor profiles. Hardisty JF. Toxicologic Pathology , 13, 91-104, 1985.

Pulmonary and hepatic health effects of inhalation of petroleum smoke. Grose EC, Stevens MA, Illing JW, Jaskot RH, Hardisty JF and Stead A. The Toxicologist, Vol 6, No. 1, March 1986.

National Toxicology Program Pathology Quality Assurance Procedures, by J.F.Hardisty and GA Boorman. In: Managing Conduct and Data Quality of Toxicology Studies, (BK Hoover, JK Baldwin and AF Uelner. NIEHS/NTP – CE Whitmire, CL Davies and DW Bristol, eds), pp 263-269. New Jersey: Princeton Scientific Publishing Co. Inc., 1986.

Pulmonary Effects Due to Short Term Exposure to Oil Fog. Selgrade MJK, Hatch GE, Grose EC, Illing JW, Stead AG, Miller FJ, Graham JA, Stevens MA and Hardisty JF. Journal of Toxicological Environmental Health, 1987 21(1-2):173-85.

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Chronic toxicity and oncogenicity study of 2,6 diethylaniline. TG Pullin, RW Naismith, JF Hardisty, EB Whorton Jr. and GL Ter Haar. The Toxicologist, Vol 8, No. 1, February 1988.

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Thyroid gland, by JF Hardisty and GA Boorman. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Oral cavity (pharynx, tongue, gingival teeth), esophagus and stomach, by HR Brown, JF Hardisty and SL Eustis. In: Pathology of the F344 Rat, (G Boorman, S Eustis, C Montgomery, M Elwell and W MacKenzie, eds), San Diego, Academic Press, 1990.

Toxicological pathology: a critical stage in study interpretation; by JF Hardisty and SL Eustis. In: Progress in Toxicology, (D Clayson, I Munro, P Shubik and J Swenberg, eds), Amsterdam, Elsevier, 1990.



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Tumors of the skin in the HRA/Skh mouse after treatment with 8-methoxysoralen and UVA radiation. JK Dunnick, PD Forbes, SL Eustis and JF Hardisty. Fund. & Appl. Tox., Vol 16, 92-102, 1991.

Proliferative lesions of the mouse lung: Progression studies in Strain A mice. JF Foley, MW Anderson, GD Stoner, BW Gaul, JF Hardisty and RR Maronpot. Experimental Lung Research, Vol.17, 157-168, 1991.

Lesions of the rodent liver. Hardisty JF. Presented at the Dose Response Relationships for Hepatocarcinogenesis in Medaka Exposed to Waterborne N-Nitrosodiethylamine. Workshop on December 15, 1993.

Procedures for peer review in toxicologic pathology. Hardisty JF. Presented at The Society of Toxicologic Pathologist 13th International Symposium on June 5-9, 1994.

Necropsy and histology in toxicologic pathology. Hardisty JF. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, July 27, 1994.

A comparison of liver tumor diagnoses from seven PCB studies in rats. Moore John A, Hardisty Jerry F, Banas Deborah A and Smith, Mary Alice. Regulatory Toxicology and Pharmacology, Vol 20, 362-370, 1994.

Neoplastic lesions of questionable significance. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 3, 1994.

Use of nasal diagrams to record nasal lesions. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Morphologic assessment of pathologic changes in the rat larynx. Hardisty JF. Presented at the 1994 Toxicology Roundtable on October 4, 1994.

Pathology peer review and PWG. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 23, 1995

Peer review in toxicology pathology. Ward JM, Hardisty JF, Hailey JR and Street CS. Toxicologic Pathology ISSN:0192-6233, Vol. 23, No. 2, 1995

Computerized pathology data – summary vs. individual. Hardisty JF. Presented at the 1995 Toxicology Roundtable in Nashville, TN on October 24, 1995.

An evaluation of changes in the olfactory epithelium and liver peroxisome proliferation in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Lake

BG, Derelanko M, Rinehart WE and Hardisty JF. The Toxicologist, Vol 30, No. 1, Part 2, March 1996.

Peer review of histopathology data. Hardisty JF. Presented at the American College of Toxicology 17th Annual Meeting in King of Prussia, PA on November 11, 1996.

Pathology peer review in assessing carcinogenicity studies. Hardisty JF. Presented at the American College of Veterinary Pathologists' Thirty- First Annual Meeting in Seattle, Washington on December 5, 1996.



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Value of the mouse carcinogenicity bioassay (Summary). Hardisty JF. Toxicologic Pathology ISSN:0192-6233, Vol. 24, No. 6, 1996, pp. 720-721.

Interaction of consultants, contract laboratories and industry-Panel Discussion with HE Black, AM Dahlem, JF Hardisty, TG Terrell. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 19, 1997.

Controversial issues in anatomic pathology. JF Hardisty. Presented at Industrial Toxicologic Pathology, University of Illinois at Urbana-Champaign, May 20, 1997.

Phenolphthalein induces thymic lymphomas accompanied by loss of the p53 wild type allele in heterozygous p53-deficient (+) mice. Dunnick JK, Hardisty JF, Herbert RA, Seely JC, Furedi-Machacek EM, Foley JF, Lacks GD, Stasiewicz S and French JE. Toxicologic Pathology, Vol. 25, No. 6., 533-540, 1997.

Diagnostic dilemmas in toxicologic pathology. Hardisty Jerry. Presented at The 22nd Annual CL Davis DVM Foundation Continuing Education Symposium at North Carolina State University, College of Veterinary Medicine in Raleigh, North Carolina on June 14-18, 1998.

Thyroid and parathyroid glands, by JF Hardisty and GA Boorman. In: Pathology of the Mouse, (RR Maronpot, GA Boorman and BW Gaul, eds), Vienna, IL, Cache River Press, 1999.

Rodent Leydig Cell Tumorigenesis: A Review of the Physiology, Pathology, Mechanisms, and Relevance to Humans. Jon C Cook, Gary R Klinefelter, Jerry F Hardisty, Richard M Sharpe and Paul MD Foster. Critical Reviews in Toxicology 1999 March;29(169-261).

The nomenclature of cell death: recommendations of an ad hoc committee of Society of Toxicologic Pathologists. Levin S, Bucci TJ, Cohen SM, Fix AS, Hardisty JF, Legrand EK, Maronpot RR and Trump BF. Toxicologic Pathology. 1999 Jul-Aug;27(4):484-490.

Controversial issues in anatomic pathology. Hardisty Jerry. Presented as a course entitled *Industrial Toxicology and Pathology* for the American Registry of Pathology at the Ramada Inn in Bethesda, MD on September 28, 1999..

Histopathology of nasal olfactory mucosa from selected inhalation toxicity studies conducted with volatile chemicals. Hardisty JF, Garman RH, Harkema JR, Lomax LG and Morgan KT. Toxicologic Pathology, Vol.27, No. 6, pp. 618-627, 1999.

Pathology Working Groups: Current Concepts. Hardisty JF. Presented at the 16th Annual Meeting of the Society of Quality Assurance in Montreal, Canada on October 9-13, 2000.

Blind Pathology – When and When Not. Hardisty JF. Presented at the 51st Annual Toxicology Roundtable Program in Asheville, NC on October 15-18, 2000.

Short-Term, Subchronic, and Chronic Toxicology Studies, by NH Wilson, JF Hardisty and JR Hayes. In: Principles and Methods of Toxicology, 4th Edition, (Wallace Hayes, ed), ISBN 1-56032-814-2, 2000.

Methods to identify and characterize developmental neurotoxicity for human health risk assessment. II: neuropathology. Garman RH, Fix AS, Jortner BS, Hardisty JF, Claudio L and Ferenc S. Environmental Health Perspectives, Vol. 109, pp. 93-100, March 2001.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

A chronic inhalation toxicity/oncogenicity study of methylethylketoxime in rats and mice. Newton PE, Wooding WL, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. *Inhalation Toxicology*, 13:1093-1116, 2001.

Carcinogenic assessment of premafloxacin in rats and mice. White KA, Daniel EM, Botta JA, Clare LJ, Barnett D, Hildebrandt P, Hardisty JF and Lucas MJ. Presented as a poster for the Society of Toxicologic Pathology and the International Federation of Societies of Toxicologic Pathologists in Orlando, Florida on June 24-28, 2001.

The Pathologist and Pathology Data. Hardisty JF. Presented at FDA CEDR on May 31, 2001.

Inhalation Toxicology of Octamethylcyclotetrasiloxane (D₄) Following a 3-month Nose-Only Exposure in Fischer 344 rats. Burns-Naas LA, Meeks RG, Kolesar GB, Mast RW, Elwell MR, Hardisty JF, Thevenaz P. *International Journal of Toxicology*. 2002 Jan-Feb;21(1):39-53.

Quality review procedures necessary for rodent pathology databases and toxicogenomic studies: The National Toxicology Program Experience. Boorman GA, Haseman JK, Waters WD, Hardisty JF and Sills RC. *Toxicologic Pathology*. 30, 88-92, 2002.

Inhalation toxicology of octamethylcyclotetrasiloxane (D₄) following a 3-month nose-only exposure in Fischer 344 rats. Burns-Naas LA, Meeks RG, Kolesar GB, Mast RW, Elwell MR, Hardisty JF and Thevenaz P. *International Journal of Toxicology*, ISSN 1091-5818, Vol. 21, No. 1, pp 39-53, 2002.

Diagnostic dilemmas in toxicologic pathology. Presented at the 5th Industrial Toxicology and Pathology Course and symposium in Chicago, IL on July 9, 2002.

Histologic artifacts & diagnostic dilemmas. Presented at the RTP Rodent Pathology Course, Research Triangle Park, NC on September 8-10, 2002.

Comparative prevalence, multiplicity, and progression of spontaneous and vinyl carbamate-induced liver lesions in five strains of male mice. Takahashi K, Dinse GE, Foley JF and Maronpot RR. *Toxicologic Pathology*, Vol 30, No. 5, pp 599-605, 2002.

Propylene glycol monomethyl ether (PGME): inhalation toxicity and carcinogenicity in Fischer 344 rats and B6C3F1 mice. *Toxicologic Pathology*, Vol 30, No. 5, pp 570-579, 2002.

An evaluation of changes and recovery in the olfactory epithelium in mice after inhalation exposure to methylethylketoxime. Newton PE, Bolte HF, Derelanko MJ, Hardisty JF and Rinehart WE. *Inhalation Toxicology*, 14:1249-1260, 2002.

The pathologist and pathology data. Hardisty JF. Presented at NIEHS, RTP, NC on February 29, 2002.

The pathologist and pathology data. Hardisty JF. Presented at the SOT Meeting in Nashville, TN on March 2002.

Propylene Glycol Monomethyl Ether (PGME); Inhalation Toxicity and Carcinogenicity in Fischer 344 rats and B6C3F1 mice. Spencer PJ, Crissman JW, Stott WT, Corley RA, Cieszlak FS, Schumann AM, Hardisty JF. *Toxicological Pathology* 2002 Sep-Oct;30(5).570-9.

Histologic artifacts and diagnostic dilemmas. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

The pathologist and pathology data. Hardisty JF. Presented at NCTR in Jefferson, AR on October 31, 2002.

The pathologist and pathology data. Hardisty JF. Presented at Health Canada in Ottawa, Canada on December 2, 2002.

Necropsy and histology techniques. Hardisty JF. Presented at FDA on January 9, 2003.

Current approaches to Peer Review and PWG. Hardisty JF. Presented at Battelle in Columbus, OH on June 5, 2003.

Characterization of intrathoracic mesothelioma in Fischer 344/N rats. Willson G, Clayton N, Hardisty J, and Pearse G. Presented as a poster for the Society of Toxicologic Pathology, 22nd Annual Meeting In Savannah, Georgia on June 15-19, 2003.

Transplacental carcinogenicity of azidothymidine in B6C3F1 mice and F344 rats. Walker DM, Hardisty JF, Ruecker FA, Funk KA, Wolfe MJ and Walker VE. Abstract No. 548, 2004 *Itinerary Planner*. Baltimore, MD: Society of Toxicology.

Comparison of automated software with conventional histopathology of liver step sections in an NTP Subchronic Bioassay. Willson GA, Joron TA, Lesniak D, Pearse G and Hardisty JF. Presented a poster at the STP Meeting in Salt Lake City, UT, June, 2004.

Automated Pathology Systems – Human Versus Machine Vision. Hardisty JF; Toxicology Roundtable, Augusta, MI. Sept. 2004.

Comparative hepatic toxicity: prechronic/chronic liver toxicity in rodents. Hardisty JF and Brix AE. *Toxicologic Pathology*, 33:35-40, 2005.

ACT/STP Pathology Course for Non-Pathologists. Hardisty JF. Speaker at ACT/STP Meeting, Lincolnshire, IL, May 10-13, 2005.

Defining a Noncarcinogenic Dose of Recombinant Human Parathyroid Hormone 1-84 in a 2-year study in Fischer 344 rats. Jolette J, Wilker CE, Smith SY, Doyle N, Hardisty JF, Metcalfe AJ, Marriott TB, Fox J, Wells DS. *Toxicological Pathology* 006;34(7):929-40.

Optimization in Pathology. Presented at RCC Scientific Workshop Basel on October 19, 2006.

Diagnostic Dilemmas in Toxicologic Pathology, Hardisty JF. Speaker, Presented at the 7th Biennial Industrial Toxicology & Pathology Short Course, Co-sponsored by the Society of Toxicologic Pathology and the University of Illinois College of Veterinary Medicine, July 23–25, 2007.

Histopathology of Hemangiosarcoma in Mice Hamsters and Liposarcomas/Fibrosarcomas in Rats Associated with PPAR Agonists. Hardisty JF, Elwell MR, Ernst H, Greaves P, Kolenda-Roberts H, Malarkey DE, Mann PC, Tellier PA. *Toxicologic Pathology*, 35:928-941, 2007.

General Principles in Necropsy and Histology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Current Practices in Toxicologic Pathology, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Chronic Progressive Nephropathy and Proliferative Lesions of the Renal Tubule, Hardisty JF. Speaker, Presented at The Third Sino-US Pharmaceutical Workshop, Toxicological Pathology in New Product Development, Boda Mansion, Beijing, May 30, 2008.

Histopathology of the Urinary Bladders of Cynomolgus Monkeys Treated with PPAR Agonists. Hardisty JF, Anderson DC, Brodie S, Cline JM, Hahn FF, Kolenda-Roberts H, Lele SM, Lowenstein LJ. *Toxicological Pathology*, 2008;36 769-776.

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"Larynx Squamous Metaplasia". A Re-consideration of Morphology and Diagnostic Approaches in Rodent Studies and its Relevance for Human Risk Assessment. Kaufmann W, Bader R, Ernst H, Harada T, Hardisty JF, Kittel B, Kolling A, Pino M, Renne R, Rittinghausen S, Schulte A, Wohrmann, T, Rosenbruch M. Presented at The 1st International ESTP Expert Workshop, Ludwigshafen, Germany; Published: *Experimental and Toxicologic Pathology*, 61 (2009) 591-603

Regulatory Perspective for Pathology Data. Manabe S, Oishi Y, Tamura K, Schorsch F, Weber K, Hardisty JF, Kuramami K. Panel Discussion: Presented at the 25th JSTP Annual Meeting, Hamamatsu, Japan, January 28, 2009. Published: *Journal of Toxicologic Pathology* 2009; 22: 209-227

Lesions in the Larynx of Wistar RccHan™: WIST Rats. Weber K, Germann PG, Iwata H, Hardisty JF, Kaufmann W, Rosenbruch M. Published: *Journal of Toxicologic Pathology* 2009; 22: 229-246

Thyroid Dysplasia in Wistar Hannover GALAS Rats. Weber K, Ernst R, Fankhauser H, Hardisty JF, Heider W, Stevens K. Published: *Journal of Toxicologic Pathology* 2009; 22: 247-254

International Prospective on Peer Review. North American Perspective presented by Hardisty JF. The 2010 Town Hall Meeting at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Optimal Routine Sampling of the Cynomolgus Monkey Nervous System in Toxicity Studies. Hardisty JF, Moore R. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

Innunohistochemical Study of Brain Tumors in Rats Treated with Acrylonitrile. Kolenda-Roberts H, Hardisty JF. Poster Presentation at the Society of Toxicologic Pathology, Chicago, IL, July 20-24, 2010.

A Commentary on the Process of Peer Review and Pathology Data Locking. McKay JS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Manabe S, Schorsch F, Terancishi M, Weber K. Published: *Journal of Toxicologic Pathology* 2010; 38: 508-510



Experimental Pathology Laboratories, Inc.

JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

Recommendations for Pathology Peer Review. Morton D, Sellers RS, Barale-Thomas E, Bolon B, George C, Hardisty JF, Irizarry A, McKay JS, Odin M, Teranishi M. Published: Journal of Toxicologic Pathology 2010; 38: 1118-1127

Pathology Working Group Review and Evaluations of Prolifer Lesions of Mammary Gland Tissues in Female Rats Fed Ammonium Perfluorooctanoate (APFO) in the diet for 2 years. Hardisty JF, Willson GA, Brown WR, McConriell EE, Frame SR, Gaylor DW, Kennedy GL, Butenhoff JL, Published: PubMed; US National Library of Medicine / National Institutes of Health. PMID: 20307141 [PubMed – indexed for MEDLINE]. Drug Chem Toxicol. 2010 Apr; 33(2): 101-137.

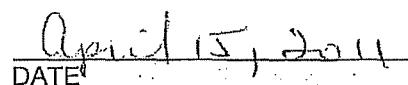
Industry-Contract Research Organization Pathology Interactions: A Perspective of Contract Research Organizations in Producing the Best Quality Pathology Report. Gosselin SJ, Palate B, Parker GA, Engelhardt JA, Hardisty JF, McDorman KS, Tellier PA, Silverman LR. Published: Journal of Toxicologic Pathology 2011; 000: 1-7.



JERRY F. HARDISTY, D.V.M.

Chief Executive Officer

Senior Pathologist



April 15, 2011

DATE



Experimental Pathology Laboratories, Inc.

**PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P.
VETERINARY PATHOLOGIST**

EDUCATION:

Washington University, St. Louis, Missouri, A.B., English Literature, 1966-1970
University of Missouri, St. Louis, Missouri, Pre-veterinary Studies, 1972-1974
University of Missouri, Columbia, Missouri, D.V.M., 1975-1979

CERTIFICATIONS/LICENSURE:

Certified by the American College of Veterinary Pathologists, 1984

PRESENT POSITION AND EXPERIENCE:

2007 – Present. Manager, EPL Northwest, Seattle, WA.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2002 – 2006. Manager, EPL Northeast, Galena, MD.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies from pharmaceutical, biotechnical, and agricultural clients. Offering histopathology and peer review services as well as organization of Pathology Working Groups. Provide interpretation of ultrastructural pathology. Consultation to clients on regulatory issues.

2000 – 2002. On-Site Consultant, DuPont Pharmaceuticals Company, Wilmington, DE.

Full-time, on-site consultant to DuPont Pharmaceuticals Company. Provided necropsy supervision and microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies by DuPont Pharmaceuticals Company.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

1999 – 2000. **Senior Projects Manager,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management and for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies for both commercial clients and the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1994 – 1999. **Director and Pathologist,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Responsible for project management, direction and technical supervision of the North Carolina Branch of EPL. Responsible for the microscopic evaluation of tissues from experimental animals used in a variety of toxicological studies. Provided support to the National Toxicology Program's Pathology Quality Assessment Program and the NTP Archives.

1990 – 1994. **Veterinary Pathologist,** Experimental Pathology Laboratories, Inc., Research Triangle Park, NC.

Duties included histopathologic interpretation of tissues from various laboratory animals used for toxicology and carcinogenesis studies.

1989 – 1990. **Pathologist,** EPL Scientific Limited, Harrogate, England.

1985 – 1989. **Veterinary Pathologist,** ICI Pharmaceuticals, Division of ICI Americas, Wilmington, Delaware.

1982 – 1989. **Staff Pathologist,** Brandywine Zoo, Wilmington, Delaware.

1982 – 1985. **Senior Lecturer,** Department of Pathobiology, University of Pennsylvania School of Veterinary Medicine.

1979 – 1982. **Resident in Pathology,** National Zoological Park, Washington, DC.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- 1974 – 1975. **Food Technologist**, Pet Foods Department, Grocery R&D, Ralston Purina Co., St. Louis, MO.
- 1970 – 1971. **Secondary School Teacher**, St. Louis, MO.

PROFESSIONAL MEMBERSHIPS:

American Veterinary Medical Association
American College of Veterinary Pathology
Society of Toxicological Pathology
British Society of Toxicologic Pathologists
C.L. Davis Foundation for the Advancement of Veterinary Pathology
North Carolina Society of Toxicology

SERVICE TO PROFESSIONAL ASSOCIATIONS:

Chairman, STP Nomenclature Subcommittee on the Mammary Gland

Member, STP Nomenclature Subcommittee on the Respiratory System
Adjunct Associate Professor at the School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology
Member, STP Symposium Committee, 1995-1998
Co-Chairman, STP Educational Committee, 1996
Chairman, STP Symposium Committee, 1998
Copy Editor, C.L. Davis Foundation Newsletter, 1998
Member, Advisory Board, C.L. Davis Foundation for the Advancement of Veterinary Pathology, 2000-2004
Member, Executive Committee, Society of Toxicologic Pathology, 2000-2004
Chairman, STP Journal Committee, 2005
Chair, Global Editorial Steering Committee, 2006-2008
President-Elect, Society of Toxicologic Pathology, 2008-2009
President, Society of Toxicologic Pathology, 2009-2010
Member, ILSI/HESI Subcommittee on Distinguishing Adverse from Adaptive, Non-Functional, and Pharmacologic Changes in Toxicology Studies, 2009-2010

SERVICE TO EDITORIAL BOARDS OF SCHOLARY JOURNALS:

Reviewer for Toxicologic Pathology, 1998-2002



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

PROFESSIONAL DEVELOPMENT/SPECIALIZED TRAINING:

Educational Activities/Special Lectures:

- | | |
|-----------|---|
| 1981 | Diseases of zoo mammals and birds. Pathology of Laboratory Animals, Washington, D.C. |
| 1982 | Pathology of zoo animals. Friends of the National Zoo, Washington, D.C. |
| 1982 | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in small animal pathology rotation. |
| 1982-1985 | Necropsy Service, University of Pennsylvania School of Veterinary Medicine, supervision of senior students and residents in large animal pathology rotation. |
| 1983 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals. |
| 1983-1984 | Philadelphia College of Pharmacy and Science. Principles of Pathology. |
| 1983-1984 | University of Pennsylvania School of Veterinary Medicine, Course 5001, General Endocrine Pathology. |
| 1983 | University of Pennsylvania School of Veterinary Medicine, Course 4501, Infectious Diseases of Dogs and Cats, Neuroendocrine Pathology. |
| 1984 | University of Pennsylvania School of Veterinary Medicine, Course 5401, Infectious Diseases of Dogs and Cats. |
| 1984 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Skin Diseases of Large Animals, Diseases of Horses. |
| 1985 | University of Pennsylvania School of Veterinary Medicine, Course 5402, Diseases of Horses. |
| 1996 | School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular. |



PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- 1997 School of Veterinary Medicine, NC State University, Department of Microbiology, Pathology and Parasitology, VMS 643: Toxicologic Pathology – Lymphoreticular.
- 1999 Chemical Industry Institute of Toxicology, Pathology Short Course for Toxicologists. Necropsy and Histology Techniques. Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays.
- 2002 Society of Toxicology, Continuing Education Course: Blood and Lymphoid Tissue: Neoplasia of Blood and Lymphoid Tissue.
- 2003 Society of Toxicology, Continuing Education Course: Integrating Toxicologic Pathology into Compound Evaluation and Risk Assessment II: Diagnostic Drift.
- 2006 International Institute of Biotechnology and Toxicology. Chennai, Tamal Nadu, India: Regulatory Toxicologic Pathology
- 2007 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine The Use of Genetically-Modified-Mice in Toxicology
- 2008 Beijing Pharma and Biotech Center (BPBC) – Sino American Pharmaceutical Professionals Association (SAPA) Beijing Workshop: Toxicologic Pathology in New Product Development. Fundamentals of General and Toxicologic Pathology and Histopathology of the Respiratory System: Nose, Larynx and Lungs.
- 2010 School of Veterinary Medicine, Purdue University. Laboratory Animal Medicine, The Use of Genetically-Modified-Mice in Toxicology and Trust me, I'm a Pathologist.
- National Institute for the Control of Pharmaceuticals and Biological Products and the Society of Toxicologic Pathology: USA-China Carcinogenicity Studies Workshop. Beijing, China. Reading the Rodent Bioassay: Problems, Pitfalls and Peer Review and Common Background Tumors of Laboratory Rodents.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Seminars and Presentations:

Canine parvovirus. Johns Hopkins Division of Comparative Medicine, Baltimore, 1980.

Parvo-like enteritis in golden lion tamarins. Primate Pathology Workshop, New Orleans, 1980.

Canine parvovirus in South American canids. American Association of Zoo Veterinarians, Washington, D.C., 1980.

Leiomyomas of the genital tract in large zoo mammals. International Academy of Pathology, Chicago, 1981.

Respiratory distress syndrome in neonatal reindeer (poster). International Academy of Pathology, Chicago, 1981.

Herpesvirus infections in old world primates. Johns Hopkins Division of Comparative Medicine, Baltimore, 1981.

Selected diseases of zoo animals. University of Pennsylvania School of Veterinary Medicine, Philadelphia, 1981.

Tuberculous osteomyelitis in captive marsupials (poster). International Academy of Pathology, Boston, 1982.

Selected diseases of zoo animals. Virginia-Maryland Regional College of Veterinary Medicine, Blacksburg, 1982.

Post mortem examination as a technique in research. Symposium on the effects of oil on birds, Stone Harbour, 1982.

Enzootic nasal tumors in sheep. Pennsylvania Diagnostic Workshop, Harrisburg, 1983.

Gross pathology of zoo animals. Eighth Annual C.L. Davis Conference in Veterinary Pathology, Philadelphia, 1984.

Peer review from the perspective of a consultant pathologist. Society for Quality Assurance Annual Meeting, Phoenix, Arizona, 1995.

Lesions of Dioxin in laboratory animals. Society of Toxicologic Pathologists 15th International Symposium, St. Louis, Missouri, 1996.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Use of genetically altered mice in short-term bioassays. The 22nd Annual C.L. Davis DVM Foundation Continuing Education Symposium, North Carolina State University, College of Veterinary Medicine, Raleigh, North Carolina, June 14-18, 1998.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Pathology of Genetically-Engineered Mice, National Institute of Health, Bethesda, Maryland, February 24-25, 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. CL Davis Foundation European Pathology Division Symposium, Nantes, France, July 1999.

Pathology of genetically-engineered mouse lines used in new short-term carcinogenesis bioassays. Wyeth Ayerst Research, Chazy, NY, November 1999.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 17-19, 2000.

Pathology Peer Review: Current Concepts. Society of Quality Assurance, 16th Annual Meeting, Montreal, Canada, October 9-13, 2000.

Background pathology of genetically-engineered mouse lines. American College of Toxicology, 21st Annual Meeting, San Diego, CA, November 13, 2000.

Background pathology of genetically-engineered mouse lines and the significance of strain variability. Pathology of Mutant Animal Models sponsored by the CL Davis Foundation, Houston, TX, February 15-17, 2001.

Pathology of Transgenic Mice. CL Davis Foundation European Division Pathology Symposium (Szent Istvan University, Budapest, Hungary), July 5-7, 2001.

Genetically-engineered mice in toxicology. Pathology of Mutant Animal Models, sponsored by the CL Davis Foundation, Houston, TX, February 13-16, 2002.

Necropsy and Histology: Current Practices in Pathology. Health Canada, Existing Substances Branch, Ottawa, Canada, March 2002.

Pathology Data and Tox-Path Issues. USFDA, May 20, 2002.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. May 21-22, 2003. Health Canada, Ottawa, Canada.

Necropsy and Histology, Current Practices in Pathology, Pathology of Transgenic Mice, Diagnostic Drift. December 2-3, 2003. Health Canada, Ottawa, Canada.

Diagnostic Dilemmas. Industrial and Toxicologic Pathology Course VI. Chicago, IL, July 18-21, 2004.

Pathology of p53 heterozygous Transgenic Mice, CL Davis Foundation, Northeast Division Meeting, December 10, 2004, Nutley NJ.

Pathology of Transgenic Mice. Korean Society of Toxicology. 2004 Annual Meeting, November 4-5, 2004, Seoul, S. Korea.

Current Practices in Pathology, Peer Review. Korean Institute of Toxicology, November 8, 2004, Daejong, S. Korea.

The PTOX Seminar Series: Transgenic Models. Forest Research Institute, October 21, 2004, Jersey City, NJ.

An Introduction to Toxicologic Pathology, Adolor Corporation, March 4, 2005, Exton, PA.

Adverse vs Non-Adverse Lesions in Toxicology Studies. Korean Institute of Toxicology, June 1, 2005, Daejong, South Korea.

Overview of Neoplastic Lesions in Rodents. Korean Association for Laboratory Animal Science, 21st International Symposium, June 3, 2005, Seoul, South Korea.

Module 3: Carcinogenesis. Alternative Onco Study Models – Update, Lecture and Practical. British Society of Toxicologic Pathology, Modular Education Programme in Toxicologic Pathology, July 15, 2005, Edinburgh, Scotland.

Transgenic Mice: Creation, Pathology and Use in Toxicology Studies. CL Davis Foundation European Division; Annual Meeting, September 6, 2005, Naples, Italy.

The Rodent Bioassay in the 21st Century: Reading the Study – Problems, Pitfalls and Peer Review. CL Davis Foundation, NorthEast Division, November 11, 2005, Nutley, NJ.

INHAND and the GESC – the New Nomenclature Project. Japanese Society of Toxicologic Pathology, February 7, 2008, Nagoya, Japan



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Pathology of Transgenic Mice. DIMS Institute of Medical Science, February 8, 2008, Ichinomiya, Japan

Trust Me, I'm a Pathologist. American College of Toxicology, Palm Springs, November 1, 2009, Palm Springs, CA.

PUBLICATIONS AND PRESENTATIONS:

Books:

Mann, P.C.: How to Buy a Used Car Without Getting Gyped. New York, New York, Harper and Row, 1975.

Book Chapters:

Salivary, Harderian and Lacrimal Glands, by S. Botts, M.P. Jokinen, E.T. Gaillard, M.R. Elwell, and P.C. Mann. In: Pathology of the Mouse (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Thymus, Spleen and Lymph Nodes, by J.M. Ward, P.C. Mann, H. Morishima, and C.H. Frith. In: Pathology of the Mouse (R.R. Maronpot, G.A. Boorman, and B.W. Gaul, eds), Vienna, IL, Cache River Press, 1999.

Managing Pitfalls in Toxicologic Pathology, by P.C. Mann, J.F. Hardisty, and M.D. Parker. In: Handbook of Toxicologic Pathology (W.M. Haschek, C.G. Rousseaux, and M.A. Wallig, eds), San Diego, CA, Academic Press, 2002.

Principles of Pathology for Toxicology Studies by Steven R. Frame and Peter C. Mann. In: Principles and Methods of Toxicology, Fifth Edition (A. Wallace Hayes, ed), Boca Raton, FL, CRC Press, 2008

Abstracts:

Mann, P.C., Bush, M., Jones, D.M., Griner, L.A., Keuhne, G.R. and Montali, R.J.: Leiomyomas of the genital tract in large zoo mammals. *Laboratory Investigation*, 1981, 44:40A.

Mann, P.C., Montali, R.J. and Bush, M.: Respiratory distress syndrome in neonatal reindeer. *Laboratory Investigation*, 1981, 44:40A-41A.

Mann, P.C., Montali, R.J. and Bush, M.: Tuberculous osteomyelitis in captive marsupials. *Laboratory Investigation*, 1982, 46-51A.

Harrison, I., Tulleners, E., Mann, P.C. and Raker, C.W.: Assessment of partial arytenoidectomy without mucosal closure of the horse. *Vet. Surgery*, 1986, 15:122.



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PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Mahler, J.F., Mann, P., Takaoka, M. and Maronpot. R.: Spontaneous lesions of the FVB/N mouse. *Tox. Path.*, 23(6), 1996, 744-745.

Torrey CE, Allen JS, Selinger K, Mann P, Miller RT and Rickert DE. Testing of Clofibrate in a 6-Month Gavage Study Using p53[±] Mice. *Toxicologic Pathology* 29S:205-207, 2001.

Jackson, K., Okasaki, K., Chihaya, Y., Sato, K., Koelling, M., Meyer, S., and Mann, P. Results of a validation carcinogenicity study using transgenic p53 +/- and transgenic ras H2 mice. The Japanese Society of Toxicology, 2004 Annual Meeting, July 2004.

Acute Adverse Effects of the Indenopyridine, CDB-4022 (Racemate), on the Ultrastructure of Sertoli Cells, Spermatocytes, and Spermatids in the Testes of Treated Rats: Comparison to the Known Sertoli Cell Toxicant, Di-n-Pentylphthalate (DPP), 38th Annual Meeting, Society for the Study of Reproduction, July 24-27, 2005, Quebec City, Quebec, Canada.

Scientific Papers:

Wagner, J.E. and Mann, P.C.: Botulism in California sea lions (*Zalophus californianus*), a case report. *Journal of Zoo Animal Medicine*, 1978, 9:142-145.

Kier, A.B., Mann, P.C. and Wagner, J.E.: Disseminated sporotrichosis in a cat. *JAVMA*, 1979, 175:202-204.

Taylor, J.L., Wagner, J.E., Kusewitt, D.F. and Mann, P.C.: *Klossiella* parasites of animals. A literature review. *Veterinary Parasitology*, 1979, 5:137-144.

Wagner, J.E., Burton, C.H., Morehouse, L.G. and Mann, P.C.: A computerized system for retrieval of case information in a veterinary diagnostic laboratory. *American Journal of Veterinary Research*, 1979, 40:336-442.

Mann, P.C., Bush, M., Appel, M.J.G., Beehler, B.A. and Montali, R.J.: Canine parvovirus infection in South American canids. *JAVMA*, 1980, 177:779-783.

Wightman, S.R., Mann, P.C. and Wagner, J.E.: Dihydrostreptomycin toxicity in the Mongolian gerbil. *Lab. Animal Science*, 1980, 30:71-75.

Montali, R.J. and Mann, P.C.: Selected diseases of zoo animals. C.L. Davis Foundation, Training Aid Issue, 1981, Vol. XI.

Montali, R.J., Mann, P.C. and Seidensticker, J.: Rabies in raccoons - Virginia. *Morbidity and Mortality Weekly Report*, 1981, 30:353-355.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

- Mann, P.C., Bush, M., Janssen, D.L. Frank, E.S. and Montali, R.J.: Clinopathologic correlations of tuberculosis in large zoo mammals. JAVMA, 1981, 179:1123-1129.
- Montali, R.J., Mann, P.C., Jones, D.M., Griner, L.A., Keuhne, G.R., Narushima, E. and Bush, M.: Leiomyomas in the genital tract of large zoo mammals. Proceedings XXIV International Symposium on the Disease of Zoo Animals, 1982, Vesprem, 117-122.
- Mann, P.C., Montali, R.J. and Bush, M.: Mycobacterial osteomyelitis in captive marsupials. JAVMA, 1982, 181:1331-1333.
- Acland, H.M., Mann, P.C., Robertson, J.L., Divers, T.J., Lichtensteiger, C.A. and Whitlock, R.H.: Toxic hepatopathy in neonatal foals. Vet Path, 1984, 21:3-9.
- Reef, V.B., Mann, P.C. and Orsini, P.G.: Echocardiographic detection of tricuspid atresia in two foals. JAVMA, 1987, 191:225-228.
- Morris, C.F., Robertson, J.L., Mann, P.C., Clark, S. and Divers, T.J.: Hemolytic uremic-like syndrome in two horses. JAVMA, 1987, 191:1453-1454.
- Tulleners, E.P., Harrison, I.W., Mann, P.C. and Raker, C.W.: Partial arytenoidectomy in the horse with and without mucosal closure. Vet Surgery, 1988, 17:252-257.
- Orsini, PG, Raker CW, Reid CF, Mann P. Xeroradiographic evaluation of the equine larynx, Am J Vet Res. 1989, 50(6):845-9.
- Tulleners, E., Mann, P., Raker, C.W., Epiglottic augmentation in the horse. Vet. Surgery, 1990, 19:181-190.
- Bader, R., Gembardt, C., Kaufmann, W., Kuttler, K., Mann, P.C., Van Zwieten, M.J. and Zurcher, C.: Part I: The Rat, 5. Integumentary System. In: International Classification of Rodent Tumours, (U. Mohr, ed), pp 1-45. International Agency for Research on Cancer, 1993.
- Hayes, J.R., Wilson, N.H., Roblin, M.C., Mann, P.C. and Kiorpis, A.L.: 28-Day continuous dosing study in minipigs with a SALATRIM structured triacylglycerol composed of stearate, acetate, and propionate. J. Agric. Food Chem., 1994, 42:563-571.



PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Dodd, D.E., Stuart, B.O., Rothenberg, S.J., Kershaw, M., Mann, P.C., James, J.T. and Lam, C.: Acute, 2-Week, and 13-Week Inhalation Toxicity Studies on Dimethylethoxysilane Vapor in Fischer 344 Rats. *Inhalation Toxicology*, 6:151-166, 1994.

Malarkey, D.E., Devereux, T.R., Dinse, G.E., Mann, P.C. and Maronpot, R.R.: hepatocarcinogenicity of chlordane in B6C3F1 and B6D2F1 male mice: evidence for regression in B6C3F1 mice and carcinogenesis independent of ras proto-oncogene activation. *Carcinogenesis*, Vol. 16, No. 11, 2617-2625, 1995.

Mann, P.C., Boorman, G.A., Lollini, L.O., McMurtin, D.N. and Goodman, D.G. Proliferative lesions of the mammary gland in rats, IS-2. In: *Guides for Toxicologic Pathology*, STP/ARP/AFIP, Washington, D.C., 1996.

Mann, P.C. Pathology peer review from the perspective of an external peer review pathologist. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 24, No. 5, 650-653, 1996.

Mahler, J.F., Stokes, W., Mann, P.C., Takaoka, M. and Maronpot, R. Spontaneous lesions in aging FVB/N mice. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 24, No. 6, 710-716, 1996.

Mann, P.C., Selected lesions of dioxin in laboratory rodents. *Toxicologic Pathology* ISSN: 0192-6233, Vol. 25, No. 1, 72-79, 1997.

Gray, L.E., Wolf, C., Mann, P., Ostby, J.S., In utero exposure to low doses of 2,3,7,8-tetrachlorodibenzo-p-dioxin alters reproductive development of female Long Evans hooded rat offspring. *Toxicology and Applied Pharmacology*, Vol 146, No. 2, 237-44, 1997.

Eckhoff G, Mann P, Gaillard E, Dykstra M, Swanson G. Naturally Developing Virus-Induced Lethal Pneumonia in Two Guinea Pigs (*Cavia porcellus*). *Contemp Top Lab Anim Sci*, 1998, 37(1):54-57.

Burns-Naas, L.A., Mast, R.W., Klykken, P.C., McCay, J.A., White, K.L., Mann, P.C. and Naas, D.J., Toxicology and humoral immunity assessment of decamethylcyclo-pentasiloxane (D₅) following a 1-month whole body inhalation exposure in Fischer 344 rats. *Toxicological Sciences*, 43:28-38, 1998.

Burns-Naas, L.A., Mast, R.W., Meeks, R.G., Mann, P.C. and Thevenaz, P., Inhalation toxicology of decamethylcyclo-pentasiloxane (D₅) following a 3-month nose-only exposure in Fischer 344 rats. *Toxicological Sciences*, 43:230-240, 1998.



Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

Mahler, JF, Flagler, ND, Malarkey, DE, Mann, PC, Haseman, JK and Eastin, W., Spontaneous and chemically induced proliferative lesions in Tg.AC Transgenic and *p53*-heterozygous mice. *Toxicologic Pathology*, Vol. 26, No. 4, 501-511, 1998.

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Experimental Pathology Laboratories, Inc.

PETER CLIFFORD MANN, D.V.M., DIPLOMATE, A.C.V.P. – CONTINUED

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A handwritten signature in black ink that reads "Peter C. Mann".

PETER C. MANN, D.V.M.
Diplomate, A.C.V.P.

APRIL 23, 2010
Date

JAMES B. NOLD
Biotechnics

Formal Education:

1985	Colorado State University Fort Collins, CO PhD Pathology
1980	The Armed Forces Institute of Pathology Washington, DC Pathology Residency Diploma
1973	Ohio State University Columbus, OH DVM

Board Certifications and Licensure:

Diplomate, American College of Veterinary Pathologists, 1980

Professional Experience:

WIL Research Laboratories, LLC/Biotechnics
Hillsborough, NC

02/09/09 - Present Position: Senior Pathologist
 Pathology

Performs microscopic examination of material obtained from various in-house studies utilizing different species. These will include acute, subacute and chronic studies. Records the microscopic findings in the on-line computer system utilizing the pathology master list of terms or microscopic lesions established for the given species or organ. Correlates the clinical pathology data with the microscopic observations. Writes the pathology summary, which includes organ weight, gross, microscopic and clinical pathology interpretations on various studies. Provides consultation to the necropsy group during the examination of individual animals sacrificed or which died on study. Provides direction and professional consultation for the department during the absence of the Director. Scientific and technical adviser for necropsy and histology labs. Maintains professional level of expertise by attending scientific meetings,

Professional Experience (Continued):

reading appropriate professional journals, and participating in professional organizations. Special interests in neuropathology include brain morphometry in developmental toxicity studies. Assists with the clinical care of study animals.

GlaxoSmithKline
Research Triangle Park, NC

2003 - 2009

Position: Director of Morphologic Pathology
Safety Assessment, Pathology

Directed the histology and necropsy service function and supervised the Manager of Necropsy and Laboratory Services. Managed the contracted histopathology workload and assisted in scheduling and assignment of studies. Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

2001 - 2003

Position: Director of Regulatory & Discovery Pathology
Safety Assessment, Pathology

Provided pathology support to both research and development functions, including consultation and collaboration on target and chemical class liability, animal model selection, and investigative and regulatory study design, as well as gross, microscopic and molecular pathologic evaluation and data interpretation of target localization and biological profiling, investigational, and regulatory studies.

Pathology Associates
A Charles River Company
Durham, NC

1997 - 2001

Position: Division Director

Was responsible for the overall operation of the North Carolina Division for Pathology Associates – A Charles River Company. Served as the senior administrator of the group and directly

Professional Experience (Continued):

supervises five doctorate level scientists and the Division Director. Served as a study pathologist and as a business development representative for the organization. Specialized in general toxicologic pathology and electron microscopy. The North Carolina Division currently has a staff of 20 personnel.

Covance Laboratories, Inc.
Pathology Department
Madison, WI

1993 – 1996

Position: Director of Pathology

Responsible for all administrative functions of the department and for the scientific direction of the Anatomical Pathology Section (which includes necropsy and histology) and the Clinical Pathology Section (which includes hematology and clinical chemistry). Directly supervised five anatomical pathologists, one clinical pathologist, the section supervisors of the Anatomic Pathology Section, and an administrative assistant. Also served as a study pathologist. Special interests in morphometry, immunopathology, and general toxicologic pathology.

Corning Hazleton, Inc.
Pathology Department
Madison, WI

1990 - 1993

Position: Pathologist

Study pathologist for acute, subchronic, chronic, and reproductive toxicology, and oncogenicity studies using rats, mice, dogs, rabbits, nonhuman primates, and domestic livestock as the experimental animals. Supervised the macroscopic examination of the test animals, evaluated the prepared tissues, and wrote the pathology portion of the study reports.

Specialized in morphometry and immunohistochemistry techniques. Radiation pathology, immunopathology, and acute toxicologic pathology were particular areas of interest.

Articles:

Quaile, M.P.; Melich, D.H.; Jordan, H.L.; Nold, J.B.; Chism, J.P.; Polli, J.W.; Smith, G.A.; Rhodes, M.C. Toxicity and toxicokinetics of metformin in rats. *Toxicology and Applied Pharmacology* **2010**, 243, 340-347.

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Herrera, J.; Gage, T.; Vigneulle, R.M.; Nold, J.B.; Dubois, A. Effects of radiation and radioprotection on small intestinal functions in canines. *Dig Dis Sci* **1995**, 40(1), 211-218.

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Articles (Continued):

Hamilton, H.B.; Severin, G.A.; Nold, J.B. Pulmonary squamous cell carcinoma with intraocular metastasis in a cat. *Journal of the American Medical Association* **1984**, 185, 307-309.

Nold, J.B.; Swanson, T.; Spraker, T.R. Bacillus piliformis infection (Tyzzer's disease) in a Colorado foal. *Journal of the American Veterinary Medical Association* **1984**, 185, 306-307.

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Books:

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Abstracts (Continued):

Palmer, T.E.; Nold, J.; Palazzolo, M.; Ryan, T. Fibrosarcomas Associated with Passive Integrated Transponder Implants," Abstract. 16th International Symposium, Society of Toxicologic Pathologists, Beaver Creek, Colorado, June 22-26, 1997.

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Miller, G.K.; Benjamin, S.A.; Nold, J.B. Developmental injury, postnatal immune function, and lymphoproliferative neoplasia in the dog. *Proceedings* 1986, 123.

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Miller, G.K.; Nold, J.B.; Benjamin, S.A. Prenatal and neonatal radiation injury and immunologic development. *Laboratory Investigation* 1986, 54, 43A.

James B. Nold

Date



Experimental Pathology Laboratories, Inc.

**ROBERT R. MARONPOT
SENIOR PATHOLOGIST**

EDUCATION:

Michigan State University, B.S., 1963
Michigan State University, D.V.M., 1965
Michigan State University, M.S., 1966
Harvard University, M.P.H., 1972

PRESENT POSITION AND BACKGROUND:

2008 – Present	Senior Pathologist, Experimental Pathology Laboratories, Inc. Research Triangle Park, NC
2007 – Present	Maronpot Consulting, LLC, 1612 Medfield Road Raleigh, NC
1992 - 2006	Chief, Laboratory of Experimental Pathology, Environmental Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1991 - 1992	Chief, Experimental Toxicology Branch, National Toxicology Program National Institute of Environmental Health Sciences, Research Triangle Park, NC
1990 - 1991	Head, Cancer Genetics & Molecular Pathology, Experimental Carcinogenesis & Mutagenesis Branch, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1989 - 1993	Board of Directors, American Board of Toxicology, Washington, D.C. University of North Carolina, Chapel Hill, N.C.
1981 - 1990	Head, Experimental Pathology, Chemical Pathology Branch, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC
1978 - 1981	Senior Fellow, Bushy Run Research Center, Carnegie-Mellon University 4400 Fifth Avenue, Pittsburgh, Pennsylvania
1975 - 1978	Head, Pathology Department, Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburgh, Pennsylvania
1974 - 1975	Head, Research Animal Facility
1974 - 1975	Acting Head, Experimental Pathology Division, Naylor Dana Institute for Disease Prevention, American Health Foundation, Valhalla, New York



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

PRESENT POSITION AND BACKGROUND: – Continued

1974 - 1975	Clinical Assistant Professor of Pathology, New York Medical College, Valhalla, New York
1975	Consultant in Veterinary Pathology, Memorial Sloan-Kettering Cancer Research Center, New York, New York
1972 - 1974	Research Fellow in Comparative Pathology, Pathology Department, Harvard Medical School and Angell Memorial Animal Hospital Boston, Massachusetts
1971 - 1972	Research Fellow in Public Health, Microbiology Department, Harvard School of Public Health, Boston Massachusetts Valhalla, New York
1968 - 1971	Head, Veterinary Medicine Department, U.S. Naval Medical Research Unit #3 Cairo, Egypt
1966 - 1968	Veterinary Laboratory Officer, Veterinary Corps, U.S. Army Pathology Division, U.S. Army Medical Research and Nutrition Laboratory, Denver, Colorado
1965 - 1966	NIH Postdoctoral Fellow, Pathology Department, Michigan State University, East Lansing, Michigan

PROFESSIONAL MEMBERSHIPS:

American College of Veterinary Pathologists

Society of Toxicologic Pathologists

Society of Toxicology

SPECIALTY BOARDS & HONORS:

Diplomate, American College of Veterinary Pathologists, 1973

Diplomate, American Board of Toxicology, 1980

Distinguished Postdoctoral Veterinary Alumnus Award from

Michigan State University College of Veterinary Medicine - 2000

President, Society of Toxicologic Pathology - 2001-2002

Editor-in-Chief, Toxicologic Pathology – 2001-2004



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007:

2007 Lectures

- Society of Toxicology Annual Meeting
Charlotte, NC – March 2007
Lectured at a Continuing Education Course
Rodent Imaging Overview for the Toxicologist
“Magnetic Resonance Imaging”
- 7th Biennial Industrial Toxicology & Pathology Short Course
University of Illinois – July 2007
“Carcinogenicity Assessment”
and
“Application of Multimodality Imaging in Toxicologic Pathology”
- American Association for Laboratory Animal Science Annual Meeting
Charlotte, NC – October 2007
The Wallace P. Rowe Lecture
“The Cancer Bioassay: Challenges for the Future”
and
Seminar on Current Imaging Modalities for Rodent Xenograft Models
“MRI Imaging Systems”
- National Academy of Science Workshop on Mouse Liver Tumors
Washington, DC – November 2007
“Mouse Models for Carcinogenicity”
- American College of Veterinary Pathologists
Savannah, Georgia – November 2007
Lectured at a Continuing Education Course
Rodent Imaging Overview for the Pathologist
“Magnetic Resonance Imaging”

2008 Lectures

- ILSI Annual Meeting
Rio Grande, Puerto Rico – January 2008
Organized symposium on “Applications of Small Animal Imaging in Toxicology Research and Testing”
Lectured on “Application of Magnetic Resonance Imaging in Toxicology and Toxicologic Pathology”
- NIEHS
February 2008
Lecture on “Comparative Medicine Branch Pathology/Case Presentations”
- Aperio Research Triangle Park Digital Pathology Seminar
May 13, 2008
Lecture on “Digital Pathology for Peer Review and Phenotyping”



Experimental Pathology Laboratories, Inc.

ROBERT R. MARONPOT, DVM, MS, MPH

SELECTED NATIONAL & INTERNATIONAL INVITED PRESENTATIONS SINCE 2007: Continued

- NTP Satellite Symposium, STP Annual meeting
Conundrums in Toxicologic Pathology
June 21, 2008, San Francisco
- 2nd East Mediterranean ICLAS Regional Meeting
“Overview of Imaging Modalities and Control of Small Animal Physiology During Live Imaging” and “Application of MRI in Toxicology and Toxicologic Pathology”
Jerusalem, Israel, December 3-4, 2008.
- TEVA Pharmaceutical Company, Israel
“The Cancer Bioassay: Past, Present, Future”
December 8, 2008

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- Editor – Toxicologic Pathology (2001- 2004)
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- Ad hoc Reviewer
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Cancer Research
American Journal of Pathology
Proceedings of the National Academy of Sciences (USA)
American Journal of Respiratory Cell & Molecular Biology
Food and Chemical Toxicology

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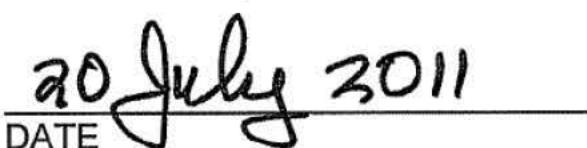
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