



**AMENDED
PATHOLOGY QUALITY ASSESSMENT REVIEW
AND PATHOLOGY WORKING GROUP (PWG)
COORDINATOR'S REPORT
FOR
LIFETIME CARCINOGENICITY STUDY
OF ACRYLONITRILE
IN SPRAGUE-DAWLEY RATS**

CONDUCTED AT

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

Submitted to:

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Experimental Pathology Laboratories, Inc.

NARRATIVE

**AMENDED
PATHOLOGY QUALITY ASSESSMENT REVIEW AND
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FOR
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Quality Assessment Review: March 14-17, 2011
Date of the Pathology Working Group: April 4- 8, 2011
PWG Coordinator: Robert R. Maronpot, DVM, MPH
Quality Assessment Pathologist: Jerry F. Hardisty, 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 Acrylonitrile (ACN) study. The ACN study was conducted by the Ramazzini Institute by inhalation administration. The study started in 1975 and involved 300 rats.

EXPERIMENTAL DESIGN AND METHODS

Twelve-week old Sprague-Dawley rats were exposed to acrylonitrile by inhalation for 4 hours per day, 5 days per week, for a total of 52 weeks and then held without further treatment for their lifetime. The numbers of animals used and their allocation to dose groups are shown in Table 1.

Table 1 – Study Design for Bioassay on Acrylonitrile Administered by Inhalation to Male and Female Sprague-Dawley Rats

Group No.	Concentration	No. Rat and Sex
I	40 ppm	30 Males & 30 Females
II	20 ppm	30 Males & 30 Females
III	10 ppm	30 Males & 30 Females
IV	5 ppm	30 Males & 30 Females
V	0 ppm	30 Males & 30 Females

Results of acrylonitrile study findings have been published previously by the Ramazzini Institute as follows:

- Maltoni, C., Ciliberti, A., Cotti, G. and Perino, G. (1988). Long-Term Carcinogenicity Bioassays on Acrylonitrile Administered by Inhalation and by Ingestion to Sprague-Dawley Rats. *Annals of the New York Academy of Sciences* 534: 179-202.
- Maltoni, C. and Ciliberti, A. (1977). Long-Term Carcinogenicity Bioassays on Acrylonitrile: Preliminary Results. *Osp. Vita* 4: 125-128.
- Maltoni, C., Ciliberti, A. and DiMaio, V. (1977). Carcinogenicity Bioassays on Rats of Acrylonitrile Administered by Inhalation and Ingestion. *Med. Lav.* 68: 401-411.

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 acrylonitrile in Sprague-Dawley rats. The request was to conduct pathology peer review analysis of proliferative and neoplastic lesions of (1) brain/central nervous system, (2) extrahepatic angiomatous lesions, and (3) Zymbal's gland, liver, and mammary gland in treated and control rats. The Quality Assessment Review included examination of all sections for hyperplastic and neoplastic changes from all male and female rats in all groups.

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

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 March 14-17, 2011 at the Ramazzini Institute. The number of slides examined during the QA review of the vinyl chloride study is listed in Table 2.

Table 2 – Number of Slides Reviewed During the QA Review

	Males	Females
Group	Slide Count	Slide Count
40 ppm	127	47
20 ppm	141	56
10 ppm	120	59
5 ppm	109	51
0 ppm	113	43
TOTAL	610	256

The Pathology Working Group (PWG) Panel met on April 7, 2011 to examine 73 tissue slides from 63 rats.

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 for neoplastic lesions in the central nervous system, subcutis, Zymbal's gland, mammary gland and liver were made consistent with current NTP nomenclature and practice.

The QA review consisted of re-examination of all proliferative lesions diagnosed by the study pathologist for brain, Zymbal's gland and mammary gland. For the liver, all originally diagnosed hepatocellular and vascular proliferative lesions were re-examined. In addition, all non-hepatic vascular proliferative lesions diagnosed by the Ramazzini pathologist were re-examined.

Pathology Working Group Review

The primary focus during the PWG review was to examine all differences in diagnoses of proliferative lesions in the brain, mammary gland, Zymbal's gland, and liver. In addition, differences of opinion between the QA and study pathologists for non-hepatic vascular proliferative lesions were reviewed.

Diagnostic criteria for brain, Zymbal's gland, mammary gland, liver, and non-hepatic angiomatous lesions used by the Pathology Working Group Panel followed internationally accepted guidelines (International Classification of Rodent Tumours. Part I: The Rat. 2. Soft Tissue and Musculoskeletal System; 7. Central Nervous System; Heart, Eye, Mesothelium; 10. Digestive System. IARC Scientific Publication No. 122. 1997; Goodman, D.G., Maronpot, R.R., Newberne, P.M., Popp, J.A. and Squire, R.A. (1994) Proliferative and Selected Other Lesions in the Liver of Rats. In: Guides for Toxicology Pathology, STP/ARP/AFIP. Washington, D.C; and Pathology of the Fischer Rat, Edited by Boorman et al., 1990. Academic Press, New York).

The PWG panel examined a total of 73 slides representing tissues from 63 rats. Panel members independently review each slide and noted their findings and personal comments on work sheets. The PWG Coordinator recorded consensus diagnoses for the relevant tissues for each rat. Occasional differences of opinion among the PWG Panel members 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 PWG panel noted that there was good

diagnostic agreement between the QA and study pathologist for mammary gland neoplasms.

The incidence of neoplastic lesions in male and female Sprague-Dawley rats is provided in Table 3.

Table 3 – Neoplastic lesions in male and female Sprague-Dawley rats exposed to acrylonitrile by inhalation for a total of 52 weeks*

	0 ppm N= 30		5 ppm N= 30		10 ppm N= 30		20 ppm N= 30		40 ppm N= 30	
	SP ^a	QA/ PWG ^b								
Mammary Gland – Males										
Fibroadenoma	0	1	0	0	0	1	0	2	0	2
Adenocarcinoma	1	0	0	0	0	0	0	0	1	1
Sarcoma	0	0	0	0	0	0	3	3	2	2
Fibroma*	0	0	0	0	1	0	2	0	3	1
Mammary Gland – Females										
Fibroadenoma	0	5	0	6	0	7	0	9	0	5
Adenocarcinoma	1	1	3	1	0	0	0	0	3	1
Sarcoma	0	0	1	1	0	0	1	1	2	2
Fibroma*	5	0	5	0	7	0	9	1	5	0
Squamous Cell Carcinoma	0	0	0	1	0	0	0	0	0	0
Brain – Males										
Microglioma	0	0	0	0	0	0	0	1	0	1
Oligodendroglioma	0	0	0	0	0	1	0	0	2	1
Brain – Females										
Malignant Reticulosis	0	0	0	0	0	0	0	1	0	1
Zymbal's Gland – Males										
Carcinoma	0	0	0	0	2	2	0	0	0	0
Zymbal's Gland – Females										
Carcinoma	0	0	0	0	1	0	1	1	0	0

^aLesion frequency represents the study pathologist diagnoses.

^bLesion frequency represents the QA and PWG Panel consensus.

*SP diagnosed fibroma and fibroadenoma as one type without distinction. Tabulated here as fibroma only for convenience. PWG classified them per NTP criteria.

Table 3 – Neoplastic lesions in male and female Sprague-Dawley rats exposed to acrylonitrile by inhalation for a total of 52 weeks*

	0 ppm N= 30		5 ppm N= 30		10 ppm N= 30		20 ppm N= 30		40 ppm N= 30	
	SP ^a	QA/ PWG ^b								
Extrahepatic Vascular Tissue – Males										
Hemangioma	0	1	0	0	0	0	2**	2	0	0
Hemangiosarcoma	1	0	0	0	1	1	0	0	0	0
Extrahepatic Vascular Tissue – Females										
Hemangioma	1**	1	0	0	1**	1	1**	0	0	0
Hemangiosarcoma	0	0	0	0	0	0	0	1	0	0

^aLesion frequency represents the study pathologist diagnoses.

^bLesion frequency represents the QA and PWG Panel consensus.

**SP diagnosed hemangioma or fibroangioma on Individual Animal Tables.

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 Acrylonitrile 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.



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



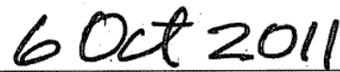
DATE

RRM:asc

REASON FOR CHANGE(S)
Pathology Quality Assessment Review
And Pathology Working Group (PWG)
Coordinator's Report
for
Lifetime Carcinogenicity Study
of Acrylonitrile
in Sprague-Dawley Rats

The amended report is being issued to add the study pathologist's data to Table 3, on pages 5 and 6 of the amended report and to include minor editorial changes to the text of the narrative portion of the final report submitted on August 17, 2011. No changes have been made to the Slide Review Work Sheets presented in Appendices A and B.


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


DATE

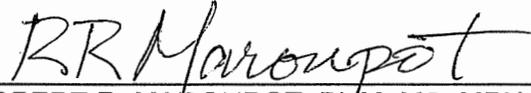
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Experimental Pathology Laboratories, Inc.

SIGNATURE PAGE

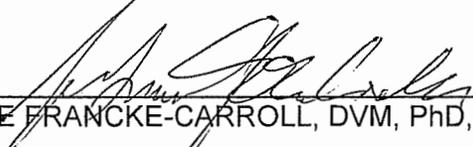
PATHOLOGY WORKING GROUP (PWG) PARTICIPANTS:



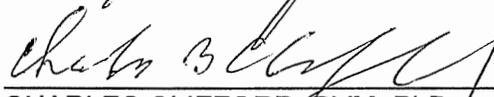
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Diplomate, ACVP, ABT
(PWG Coordinator)



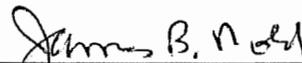
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SABINE FRANCKE-CARROLL, DVM, PhD, FIATP



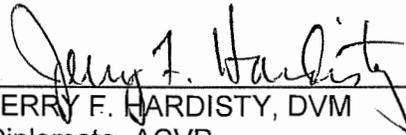
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Experimental Pathology Laboratories, Inc.

APPENDIX A
SLIDE REVIEW WORK SHEETS
MALE

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
431		4	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - METAS PR KIDN, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
432		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
433		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
433	Cont'd	4	LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
434		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
435		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
436		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 5M

TMT 9

Dosage 0 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
436	Cont'd	5	MAMMARY GL - ADENOCARC, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	
			SUBCUTIS - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	SKIN, SUBCUTANEOUS TISSUE: HEMANGIOMA (A)	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
437		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
438		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - BEN MENINGIOMA, PRESENT	AGREE[PWG]	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
438	Cont'd	4	ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
439		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
440		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
441		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
442		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
443		1	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
444		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - ANGIOECTASIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
445		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 5M

TMT 9

Dosage 0 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
445		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
446		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
447		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
448		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
448		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
449		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
450		2	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
450	Cont'd	2	MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
451		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
452		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
453		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 5M

TMT 9

Dosage 0 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
453	Cont'd	4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
454		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
455		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - ANGIOECTASIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
456		3	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Laboratory

Group 5M

Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #

CAS #

Dosage 0 PPM

Sacrifice

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>
457		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
458		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
459		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
460		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 9

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
460		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 7

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
331		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
332		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
333		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
334		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 7

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
334		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
335		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
336		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
337		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 4M

TMT 7

Dosage 5 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
337		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
338		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
339		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
340		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 7

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
343	Cont'd	4	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
344		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
345		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 7

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
345	Cont'd	4	LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
346		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - GLANDULAR HYPE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
347		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
348		3				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 4M

TMT 7

Dosage 5 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
348		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
349		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
350		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 4M

TMT 7

Dosage 5 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
350	Cont'd	4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
351		4	BRAIN - NORMAL	MISSING SLIDE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	MISSING SLIDE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	MISSING SLIDE	NOT REVIEWED	
352		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
353		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 4M

TMT 7

Dosage 5 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
354		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
355		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
356		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
357		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 7

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
360	Cont'd	3	LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
232		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - EOSINOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
233		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
233	Cont'd	4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
234		1	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
235		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIOMATOUS HY, PRESENT	LIVER - ANGIECTASIS (-)	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
236		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
236		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - METAS PR KIDN, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
237		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
238		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
239		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 5

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
239	Cont'd	4	LIVER - ANGIO HYP ATYP, PRESENT	LIVER - ANGIECTASIS (-)	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
240		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
241		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - FIBROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
241	Cont'd	4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
242		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CARCINOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
243		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
244		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
244		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
245		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
246		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
247		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 5

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
247		4	BRAIN - ANGIOMATOUS HY, PRESENT	BRAIN - MALIGNANT OLIGODENDROGLIOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
248		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
249		1	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
250		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
250		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
251		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
252		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
253		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
254		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
255		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
256		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 3M

TMT 5

Dosage 10 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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	Cont'd	4	LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
257		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
258		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CARCINOMA, PRESENT	AGREE	NOT REVIEWED	
259		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 5

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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	Cont'd	6	LIVER - NORMAL	AGREE	NOT REVIEWED	
			SUBCUTIS - HAEMANGIOSARCO, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
260		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
131		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - MAL MENINGIOMA, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
132		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
133		4	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			SPLEEN - HMNG OR FBROAN, PRESENT	SPLEEN - HEMANGIOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - MISSING	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
133	Cont'd	4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
134		7	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
135		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
136		4	BRAIN - MAL ASTROCYTOM, PRESENT	BRAIN - GLIOMA MALIGNANT (-) [MALIGNANT MICROGLIOMA] {PWG}	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
136	Cont'd	4	LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
137		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
138		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
139		8	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
139	Cont'd	8	LIVER - ANGIOMATOUS HY, PRESENT	NOT PRESENT IN SECTION (-)	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
140		8	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - LYMPH LEUKAEMI, PRESENT	LIVER - LEUKEMIA MONONUCLEAR (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
141		4	ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
141	Cont'd	4	LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
142		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
143		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
144		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
144		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - ANGIOECTASIS, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
145		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
146		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 2M

TMT 3

Dosage 20 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
146	Cont'd	6	MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
147		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
148		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			SKIN - HMNG OR FBROAN, PRESENT	SKIN - HEMANGIOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 2M

TMT 3

Dosage 20 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
149		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
150		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
151		5	BRAIN - MYELOCIT LEUK, PRESENT	AGREE	NOT REVIEWED	
			LIVER - FATTY CHANGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
152		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
152		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
153		8	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
154		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
154	Cont'd	4	MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
155		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
156		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
157		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
157	Cont'd	6	LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - ADNMA OR PAPLM, PRESENT	ZYMBAL'S GLAND - CYST (-)[PWG] {DISTENDED WITH KERATIN} {LEFT SECTION}	AGREE WITH REVIEWING PATHOLOGIST	
			ZYMBALS GL - CYST, PRESENT	AGREE[RIGHT SECTION]	AGREE WITH STUDY PATHOLOGIST	
158		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
159		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
160		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 3

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
160		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
31		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
32		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
33		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - MISSING	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
34		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
34	Cont'd	5	LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
35		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
36		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
37		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
37		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - HYP HEMATOP CE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
38		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
39		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 1

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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	Cont'd	6	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
40		7	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
41		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	SKIN, SUBCUTANEOUS TISSUE - FIBROMA (A)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
42		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
42		4	BRAIN - MAL OLIGODENDR, PRESENT	BRAIN - GLIOMA MALIGNANT (-) {MALIGNANT MICROGLIOMA} {PWG}	AGREE WITH REVIEWING PATHOLOGIST	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
43		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
44		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - LYMPH LEUKAEMI, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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	Cont'd	5	ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
45		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CYST, PRESENT	AGREE	NOT REVIEWED	
46		7	BRAIN - GLIAL CL HYPER, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
47		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
48		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - DIFFUSED HYPER, PRESENT	LIVER - BASOPHILIC FOCUS (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
49		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
50		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
50		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
51		3	BRAIN - MISSING	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
52		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - LYMPH LEUKAEMI, PRESENT	LIVER - LEUKEMIA MONONUCLEAR (-)	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
53		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
53		4	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
54		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
55		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - MISSING	AGREE	NOT REVIEWED	
56		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE

Chemical #

Laboratory

CAS #

Group 1M

TMT 1

Dosage 40 PPM

Sex & Species MALE SPRAGUE DAWLEY RAT

Sacrifice

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>
56	Cont'd	4	LIVER - HISTIO SARC, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
57		4	BRAIN - MAL OLIGODENDR, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
58		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	
59		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1M
Sex & Species MALE SPRAGUE DAWLEY RAT

TMT 1

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
59		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - ADNMA OR PAPLM, PRESENT	NOT PRESENT IN SECTION (-)[PWG]	TISSUE NORMAL	
			ZYMBALS GL - CYST, PRESENT	AGREE	TISSUE NORMAL	
60		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - NORMAL	AGREE	NOT REVIEWED	



Experimental Pathology Laboratories, Inc.

APPENDIX B
SLIDE REVIEW WORK SHEETS
FEMALE

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
401		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
402		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
403		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
404		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			SUBCUTIS - HMNG OR FBROAN, PRESENT	SKIN, SUBCUTANEOUS TISSUE - HEMANGIOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
405		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
405	Cont'd	1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
406		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
407		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
408		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
409		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
410		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
411		1				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
411		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
412		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
413		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - METAS PR ADREN, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
414		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
415		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
416		3				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
416		3	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
417		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
418		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
419		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
420		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
420	Cont'd	1	MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
421		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
422		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			SKIN, SUBCUTANEOUS TISSUE - FIBROMA (A)[PWG]		NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
423		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
424		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
425		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
426		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
427		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
428		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
429		3	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
430		4				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 5F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 10

Chemical #
CAS #
Dosage 0 PPM
Sacrifice

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>
430		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
301		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
302		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
303		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
304		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
305		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
305	Cont'd	1	LIVER - NEOPLASTIC NOD, PRESENT	LIVER - BASOPHILIC FOCUS (-)[PWG]	NOT PRESENT IN SECTION (-)	
				LIVER - EOSINOPHILIC FOCUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
306		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
307		0	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - MISSING	AGREE	NOT REVIEWED	
308		1	MENINGES - MISSING	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
309		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	
310		2	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
310		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	MAMMARY GLAND - FIBROADENOMA (A,B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
311		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
312		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
313		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
314		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
315		1				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
315		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
316		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
317		2	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
318		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
319		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
319	Cont'd	5	MENINGES - BEN MENINGIOMA, PRESENT	AGREE[PWG]	NOT REVIEWED	
320		3	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	MAMMARY GLAND - FIBROADENOMA (A,B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
321		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
322		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
323		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			LIVER - LYMPH LEUKAEMI, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
324		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
325		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
326		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
327		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
328		2	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 4F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 8

Chemical #
CAS #
Dosage 5 PPM
Sacrifice

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>
328	Cont'd	2	MENINGES - NORMAL	AGREE	NOT REVIEWED	
329		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
330		7	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	AGREE[PWG]	MAMMARY GL: INFLAMMATION (-)	
			<Inserted Finding>		MAMMARY GL: SQUAM CEL CARC (-)	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
202		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	AGREE	MAMMARY GL: FIBROADENOMA (-)	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
203		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
204		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
205		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
206		1				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
206		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
207		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
208		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			UTERUS - HMNG OR FBROAN, PRESENT	UTERUS - HEMANGIOMA (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	MAMMARY GLAND - FIBROADENOMA (B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
209		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
210		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
210	Cont'd	3	MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
211		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
212		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - ADNMA OR PAPLM, PRESENT	ZYMBAL'S GLAND - CARCINOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
213		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
214		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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	Cont'd	2	MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
215		2	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
216		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
217		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
218		6	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CARCINOMA, PRESENT	ZYMBAL'S GLAND - HYPERPLASIA, SQUAMOUS (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
219		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
220		2	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
221		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
222		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
223		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
224		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
226		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - BEN MENINGIOMA, PRESENT	AGREE[PWG]	NOT REVIEWED	
227		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	MAMMARY GLAND - FIBROADENOMA (A,B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
228		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
229		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
230		3				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 3F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 6

Chemical #
CAS #
Dosage 10 PPM
Sacrifice

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>
230		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
101		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
102		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
103		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
104		4	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
105		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
106		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
107		1	BRAIN - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
			ZYMBALS GL - CARCINOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
108		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
109		3	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
110		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
111		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
112		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
113		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
114		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)	AGREE WITH REVIEWING PATHOLOGIST	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
114	Cont'd	2	MENINGES - NORMAL	AGREE	NOT REVIEWED	
115		5	BRAIN - NORMAL	AGREE	NOT REVIEWED	
116		7	MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
117		1	BRAIN - MAL OLIGODENDR, PRESENT	BRAIN - RETICULOSIS MALIGNANT (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
118		1	BRAIN - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
119		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
119		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
120		2	BRAIN - INFLAMMATION, PRESENT	AGREE	NOT REVIEWED	
			KIDNEY - HMNG OR FBROAN, PRESENT	KIDNEY - HEMANGIOMA (-)[PWG]	KIDNEY: HEMANGIOSARC (-)	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
121		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - SARCOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
122		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
123		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
123	Cont'd	1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
124		0	BRAIN - MISSING MENINGES - MISSING	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
125		1	BRAIN - HEMORRAGE, PRESENT MENINGES - NORMAL	AGREE AGREE	NOT REVIEWED NOT REVIEWED	
126		2	BRAIN - NORMAL MAMMARY GL - FIBROM FIBROAD, PRESENT	AGREE MAMMARY GLAND - FIBROADENOMA (A)[PWG]	NOT REVIEWED AGREE WITH REVIEWING PATHOLOGIST	
127		3	MENINGES - NORMAL BRAIN - GLIAL CL HYPER, PRESENT MAMMARY GL - FIBROM FIBROAD, PRESENT MENINGES - NORMAL	AGREE NOT PRESENT IN SECTION (-)[PWG] SKIN, SUBCUTANEOUS TISSUE - FIBROMA (A)[PWG] AGREE	NOT REVIEWED TISSUE NORMAL AGREE WITH STUDY PATHOLOGIST NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 2F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 4

Chemical #
CAS #
Dosage 20 PPM
Sacrifice

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>
128		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
129		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
130		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
2		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
3		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
4		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
5		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
6		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
7		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
8		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	MAMMARY GLAND - ADENOMA (C)[PWG]	NOT PRESENT IN SECTION (C)	
			MAMMARY GL - FIBROM FIBROA2, PRESENT	MAMMARY GLAND - FIBROADENOMA (A,B)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
9		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
10		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
11		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
11	Cont'd	1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
12		3	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
13		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			BRAIN - NECROSIS, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
14		7	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MAMMARY GL - SARCOMA, PRESENT	AGREE[PWG]	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
15		2				

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
15		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - ADENOCARC, PRESENT	NOT PRESENT IN SECTION (A)[GLANDS TRAPPED IN SARCOMA] {PWG}	AGREE WITH REVIEWING PATHOLOGIST	
			MAMMARY GL - SARCOMA, PRESENT	AGREE[PWG]	AGREE WITH STUDY PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
16		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
17		6	BRAIN - MAL OLIGODENDR, PRESENT	BRAIN - RETICULOSIS MALIGNANT (-)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
18		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
18	Cont'd	1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
19		0	BRAIN - MISSING	AGREE	NOT REVIEWED	
			MENINGES - MISSING	AGREE	NOT REVIEWED	
20		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
21		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
22		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
23		2	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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	Cont'd	2	MAMMARY GL - FIBROM FIBROAD, PRESENT	MAMMARY GLAND - FIBROADENOMA (A)[PWG]	AGREE WITH REVIEWING PATHOLOGIST	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
24		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
25		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
26		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
27		1	BRAIN - NORMAL	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	
28		2	BRAIN - NORMAL	AGREE	NOT REVIEWED	

SLIDE REVIEW WORKSHEET

Study Title ACRYLONITRILE
Laboratory
Group 1F
Sex & Species FEMALE SPRAGUE DAWLEY RAT

TMT 2

Chemical #
CAS #
Dosage 40 PPM
Sacrifice

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>
28	Cont'd	2	MENINGES - NORMAL	AGREE	NOT REVIEWED	
29		1	BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
30		1	MENINGES - NORMAL	AGREE	NOT REVIEWED	
			BRAIN - HEMORRAGE, PRESENT	AGREE	NOT REVIEWED	
			MENINGES - NORMAL	AGREE	NOT REVIEWED	



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.
15. **Clifford CB**, Samples, sample selection, and statistics: living with uncertainty. *Lab Anim (NY)* (2001 Nov) 30(10):26-31
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.

21. Crippa,L.; Gobbi,A.; Ceruti,R.M.; **Clifford,C.B.**; Remuzzi,A.; Scanziani,E. Ringtail in suckling Munich Wistar Fromter rats: A histopathologic study. *Comparative Medicine* 50(5):536-539, 2000.
22. **Clifford CB**, Samples, sample selection, and statistics: living with uncertainty. *Lab Anim (NY)* 30(10):26-31, 2001
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.
30. [In Press withheld under Exemptions B4 and B6]
31. Schaffer BS, Grayson MH, Wortham JM, Kubicek CB, McCleish AT, Prajapati SI, Nelson LD, Brady MM, Jung I, Hosoyama T, Sarro LM, Hanes MA, Rubin BP, Michalek JE, **Clifford CB**, Infante AJ, Keller C, Immune competency of a hairless mouse strain for improved preclinical studies in genetically engineered mice. *Mol Cancer Ther* (2010 Aug) 9(8):2354-64

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.
5. Magnuson, D.K., Zaucha, G.M., **Clifford, C.B.**, and Korte, D.W., Primary Dermal Irritation of Physostigmine Salicylate, Physostigmine Free-Base, and Pyridostigmine Bromide in New Zealand White Rabbits. Institute Report #438, Letterman Army Institute of Research, January 1990.
6. Coppes, V.G., Gomez, C.L., **Clifford, C.B.**, Ferraris, S., and Korte, D.W., Toxic Potential of Nitroguanidine on Reproduction and Fertility in Rats, Institute Report #434, Letterman Army Institute of Research, May 1990.
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 Schistosomiasis 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

Curriculum Vitae

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

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.

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

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

- 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.

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-fluorouracil 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

Dr. Sabine FRANCKE-CARROLL

Veterinary Medical Officer / Expert Toxicologic Veterinary Regulatory Review Pathologist

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 Acq 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 and 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.

Greaves P., Martin J., Michel M.C. and Mompon P. (1984): Cardiac hypertrophy in dog and rat induced by oxfenicine an agent which modifies muscle metabolism. In: *Diseases, Metabolism and Reproduction in the Toxic Response to drugs and Other Chemicals*. *Arch.Toxicol.*, Suppl. 7, 488-493.

Irisarri E., Kessedjian M.J., Charuel C., Faccini J.M., Greaves P., Monro A.M., Nachbaur J. and Rabémampianina Y. (1984): The preclinical toxicity of Dazoxiben, a specific inhibitor of thromboxane A2 synthetase. In: *Disease, Metabolism and Reproduction in the Toxic Response to Drugs and Other Chemicals*. *Arch.Toxicol.*, Suppl. 7, 363-364.

Taradach C. and Greaves P. (1984): Spontaneous eye lesions in laboratory animals. Incidence in relation to age. *CRC Crit.Rev.Toxicol.*, **12**, 121-147.

Greaves P. and Boiziau J.L. (1984): Altered patterns of mucin secretion in gastric hyperplasia in mice. *Vet.Pathol.*, **21**, 224-228.

Greaves P., Filipe M.I., Abbas S. and Ormerod M.G. (1984): Sialomucins and carcinoembryonic antigen in the evolution of colorectal cancer. *Histopathology*, **8**, 825-834.

Irisarri E., Kessedjian M.J., Charuel C., Faccini J.M., Greaves P., Monro A.M., Nachbaur J. and Rabémampianina Y. (1985): Dazoxiben, a prototype inhibitor of thromboxane synthesis, has little toxicity in laboratory animals. *Hum.Toxicol.*, **4**, 311-315.

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.

- Greaves P., Martin J.M. and Rabémampianina Y. (1985): Malignant fibrous histiocytoma in rats at site of implanted millipore filters. *Am.J.Pathol.*, **120**, 207-214.
- Spencer A.J. Andreu M. and Greaves P. (1986): Neoplasia and hyperplasia of pancreatic endocrine tissue in the rat: An immunocytochemical study. *Vet.Pathol.*, **23**, 11-15.
- Greaves P., Irisarri E. and Monro A.M. (1986): Hepatic foci of cellular and enzymatic alteration and nodules in rats treated with clofibrate or diethylnitrosamine followed by phenobarbitone: Their rate of onset and their reversibility. *J.N.C.I.*, **76**, 475-484.
- Masson M.T., Villanove F. and Greaves P. (1986): Histological demonstration of wheat germ lectin binding sites in normal and ANIT-treated rats. *Arch.Toxicol.*, **59**, 121-123.
- Spencer A. and Greaves P. (1987): Polyarteritis in a beagle dog colony. *J.Comp.Pathol.*, **97**, 122-128.
- Mompon P., Greaves P., Irisarri E., Monro A.M. and Bridges J.W. (1987): A cytochemical study of the livers of rats treated with diethylnitrosamine/phenobarbital, with benzidine/phenobarbital, with phenobarbital, or with clofibrate. *Toxicology*, **46**, 217-236.
- Greaves P. (1987): Safety evaluation prior to administration of drugs to man. *Lab.Anim.*, **21**, 166.
- Greaves P. (1989): Malignant fibrous histiocytoma, rat. In: Monograph on Pathology of Laboratory Animals. Integument and Mammary Glands. T.C. Jones, U.Mohr and R.D. Hunt (Eds), pp.106-112. Springer-Verlag, Berlin.
- de la Iglesia F.A. and Greaves P. (1989): Role of toxicokinetics in drug safety evaluations. In: Toxicokinetics and New Drug Development. A. Yacobi J.P. Skelly and Y.K. Batra (Eds), chap 2, pp 21-32, Pergamon Press, New York.
- Macallum G.E., Smith G.S., Barsoum N.J., Walker R.M. and Greaves P. (1989): Renal and hepatic toxicity of a benzopyran-4-one in the cynomolgus monkey. *Toxicology*, **59**, 97-108.
- Albassam M.A., Houston B.J., Greaves P. and Barsoum N.J. (1989): Polyarteritis in a beagle. *J.Am.Vet.Med.Assoc.*, **194**, 1595-1597.
- Macallum G.E., Walker R.M., Barsoum N.J., Smith G.S. and Greaves P. (1989): Preclinical toxicity studies of an adenosine agonist, CI-936. *Toxicologist*, **9**, 178.
- Walker R.M., Clarke D.W., Smith G.S., Macallum G.E. Barsoum N.J. and Greaves P. (1989): Hepatotoxicity of tacrine in animal models. *Toxicologist*, **9**, 197.
- Greaves P. and Barsoum N. (1990): Tumours of soft tissues. In: Pathology of Tumours of Laboratory Animals, Vol 1, Tumours of the Rat. V.S. Turusov and U. Mohr (Eds), *2nd Edition*, pp 597-623, IARC, Lyon.
- Westwood F.R., Greaves P. and Iswaran T.J. (1990): Arterial and venous changes in rats following administration of a phosphodiesterase inhibitor. *Toxicol.Pathol.*, **18**, 699.
- Westwood F.R., Iswaran T.J. and Greaves P. (1990): Pathologic changes in blood vessels following administration of an inotropic vasodilator (ICI 153,110) to the rat. *Fundam.Appl.Toxicol.*, **14**, 797-809.
- Westwood F.R., Iswaran T.J. and Greaves P. (1991): Long-term effects of an inotropic phosphodiesterase inhibitor (ICI 153,110) on the rat salivary gland, Harderian gland and intestinal mucosa. *Toxicol.Pathol.*, **19**, 214-223.
- Greaves P., Faccini, J.M. and Courtney C.L. (1992): Proliferative lesions in soft tissues in rats, MST-1. In: Guides for Toxicologic Pathology, STP/ARP/AFIP, Washington DC.
- Carlton, W.W., Ernst, H., Faccini, J.M., Greaves, P., Krinke, G.L., Long, P.H., Maekawa, A., Newsholme, S.J. and Weisse, G. (1992): Soft tissue and musculoskeletal system. In: Mohr, U., Capen, C.C., Dungworth, D.L., Griesemer,

R.A., Ito, N., and Turusov, V.S. (Eds.) International Classification of Rodent Tumours, Part I, The Rat. IARC Scientific Publication No. 122, Lyon.

Lazenby C.M., Westwood F.R. and Greaves P. (1993): Crescentic cataracts in Alderley Park rats. *Vet.Pathol.*, **30**, 70-74.

Greaves, P., Goonetilleke, R., Nunn, G., Topham, J and Orton, T. (1993): Two year carcinogenicity study of tamoxifen in Alderley Park Wistar-derived rats. *Cancer Res.*, **53**, 3919-3924

Greaves P. (1993): Pathological techniques in toxicology. In: General and Applied Toxicology. B. Ballantyre, T. Marrs, and P. Turner (Eds), vol. 1, chap. 12, pp. 245-265, Stockton Press, New York.

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Greaves P. and Seely J.C. (1996): Non-proliferative lesions of soft tissues and skeletal muscle in rats, MST-1. In: Guides for Toxicologic Pathology, STP/ARP/AFIP, Washington, DC.

Greaves P. (1997): Tumors of soft tissues including cardiovascular system. In: Pathology of Neoplasia and Preneoplasia in Rodents. P. Bannasch and W. Gössner (Eds), chap. 12, pp. 183-201, EULEP Color Atlas, vol. 2, Schattauer, Stuttgart.

Greaves P. (1997): Urinary system. In: Target Organ Pathology: A Basic Text. J.A. Turton and J. Hooson (Eds), chap. 4, pp. 99-139, Taylor and Francis, London.

Greaves P. (1998): Patterns of drug-induced cardiovascular pathology in the beagle dog: relevance for humans. *Exp.Toxicol.Pathol.* **50**, 283-293.

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Ernst, H., Carlton, W.W., Courtney, C., Rinke, M., Greaves, P., Isaacs, K.R., Krinke, G., Konishi, Y., Mesfin, G.M. and Sandusky, G. (2001): Soft tissue and skeletal muscle. In: Mohr, U. (Ed), International Classification of Rodent Tumours. The Mouse, pp. 361-388. Springer Verlag, Heidelberg.

Pyrah, I.T., Kalinowski, A., Jackson, D., Davies, W., Aldridge, A. and Greaves, P. (2001): Pathology of two structurally related inhibitors of oxidosqualene cyclase in the dog and mouse. *Toxicol.Pathol* **29**, 174-179.

Greaves, P., Edwards, R., Cohen, G.M. and MacFarlane, M. (2001): Have you seen this? Diffuse hepatic apoptosis. *Toxicol.Pathol.*, **29**, 398-400.

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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[In Press withheld under Exemptions B4 and B6]



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 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.



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 preceptee 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



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.



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-Xylidine 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

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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.

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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.



JERRY F. HARDISTY, DVM, DACVP

PUBLICATIONS AND PAPERS – Continued

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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-Nitrosodietylamine. 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.



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.

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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, Lowenstine LJ. Toxicological Pathology, 2008;36 769-776.

Ocular Collection Protocol for the Laboratory Rabbit, Dog, and Monkey. Render JA, Dubielzig RR, Dunn DG, Hardisty JF, Moore RR, Sabio DA. Presented as a poster for the 6th European Congress of Toxicologic Pathology, Edinburgh, Scotland on September 24 - 26, 2008.

"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, Kölling 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, Kuranami 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.

Innumohistochemical 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



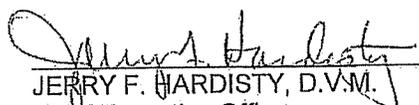
JERRY F. HARDISTY, DVM, DACVP

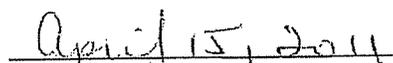
PUBLICATIONS AND PAPERS – Continued

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 Ammoni Perfluorooctanoate (APFO) in the diet for 2 years. Hardisty JF, Willson GA, Brown WR, McConnell 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


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.



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.



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



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, Tamil 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.



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.



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 Institution 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.



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

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 Gypped*. 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.

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.

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A handwritten signature in cursive script that reads "Peter C. Mann".

PETER C. MANN, D.V.M.
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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 | <u>Position:</u> 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.

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Date



**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, Pittsburg, Pennsylvania
1975 - 1978	Head, Pathology Department, Chemical Hygiene Fellowship, Carnegie-Mellon Institute of Research, 4400 Fifth Avenue, Pittsburg, 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



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

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”

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

EDITORIAL REVIEW BOARD:

- Editor – Toxicologic Pathology (2001- 2004)
- Editorial Board – Toxicologic Pathology (1986-2001)
- Section Editor, Laboratory Animal Pathology (1996-2001)
- Editorial Board – Drug and Chemical Toxicology (1986-1992)
- Editorial Board – Fundamental and Applied Toxicology (1985-1991)
- Editorial Review Board – Environmental Health Perspectives (1985-1992) (1994-1997)
- Editorial Board – Toxicology (1988-1998)
- Senior Advisor – Toxicologic Pathology (2005-present)
- Editorial Board – Experimental & Toxicologic Pathology (2001-present)

EDITORIAL ACTIVITIES:

- Ad hoc Reviewer
- Comparative Medicine
- Carcinogenesis
- Molecular Carcinogenesis
- Cancer
- International Journal of Cancer
- Toxicological Sciences
- 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

ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS:**

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

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Maronpot RR, Michael SA, and Botros BAM, 1974. Blood Parasites in Egyptian Domestic Animals. *J. Egypt. Vet. Med. Assoc.* 34:301-308.

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

Wilson WE, Hudson PM, Kanamatsu T, Walsh TJ, Tilson HA, Hong JS, Maronpot RR, and Thompson M, 1986. Trimethyltin- Induced Alterations in Brain Amino Acids, Amines and Amine Metabolites: Relationship to Hyperammonemia. *NeuroToxicology* 7(3):63-74.

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

Mitsumori K, Dittrich KL, Stefanski S, Talley FA, and Maronpot RR, 1987. Immunohistochemical and Electron Microscopic Study of Meningeal Granular Cell Tumors in Rats. *Vet. Path.* 24:356-359.

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ROBERT R. MARONPOT, DVM, MS, MPH**PUBLICATIONS AND PAPERS: – Continued**

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A handwritten signature in black ink that reads "RR Maronpot" with a long horizontal flourish extending to the right.

ROBERT R. MARONPOT, D.V.M.
Senior Pathologist

A handwritten date in black ink that reads "20 July 2011".

DATE