DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Mail Stop HFS-657
5001 Campus Drive
College Park, MD 20740-3835

March 29, 2017

Pg. 2

Dennis R. Lawyer, Health Physicist
U.S. Nuclear Regulatory Commission
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, PA 19406-2713

RLJ

19-30771-01

NRC License No. ~~01-15770-01~~
Docket No. 03036120

REC RG 1 03/30/17 PM 12:35

RE: NRC License Amendment Request

Dear Mr. Lawyer,

This correspondence is a request for a license amendment regarding the removal of two former Authorized Users who have retired from Federal service and the addition of another Authorized User at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN).

FDA CFSAN is requesting the removal of two retired scientists, Dr. Steven Monday (11E) and Dr. Mona Calvo (11F) from the license. Additionally, FDA CFSAN is requesting the addition of Dr. Michael Myers as an Authorized User of hydrogen-3 and carbon-14. A summary of training and experience as well as a *Curriculum Vitae* for Dr. Myers is attached for your consideration.

Also, please note that the address for the Wiley Building has been changed by the local planning commission (the Maryland-National Capital Park and Planning Commission). The building's physical location remains the same; however, the new street address is 5001 Campus Drive, College Park, MD, 20740.

Should you have any questions on this matter, please contact our Radiation Safety Officer, Charles Watts at 301-694-6000 or cwatts@clymenvironmental.com or contact me at 240-402-1599 or james.zelinsky@fda.hhs.gov.

Sincerely,

James Zelinsky
Occupational Safety and Health Manager

Enclosure

594437

NMSS/RGN1 MATERIALS-002

SUMMARY OF TRAINING AND EXPERIENCE

NAME: **Michael J. Myers, Ph.D.** **TITLE: Research Immunologist**

TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB	FORMAL COURSE
Principles and practices of radiation protection	**Indiana University** **Medical College of VA** **University of Illinois** **NIH** **FDA**	1980 – 1984* 1984 - 1986* 1986 – 1988* 1988 – 1990*†‡ 1990- 2000*	1980 - 1984 1984 - 1986 1986 - 1988 1988 – 1990 1990- 2000	*1 hr each year as part of a comprehensive annual training
Radioactivity measurement standardization and monitoring techniques and instruments	**Indiana University** **Medical College of VA** **University of Illinois** **NIH** **FDA**	1980 – 1984* 1984 - 1986* 1986 – 1988* 1988 – 1990*†‡ 1990- 2000*	1980 - 1984 1984 - 1986 1986 - 1988 1988 – 1990 1990- 2000	† NIH Radiation Safety Course for Radiation Workers (40 hr)
Mathematics and calculations basic to the use and measurement of radioactivity	**Indiana University** **Medical College of VA** **University of Illinois** **NIH** **FDA**	1980 – 1984* 1984 - 1986* 1986 – 1988* 1988 – 1990*†‡ 1990- 2000*	1980 - 1984 1984 - 1986 1986 - 1988 1988 – 1990 1990- 2000	‡ NIH Authorized Radiation User Training (160 hr)
Biological effects of radiation	**Indiana University** **Medical College of VA** **University of Illinois** **NIH** **FDA**	1980 – 1984* 1984 - 1986* 1986 – 1988* 1988 – 1990*†‡ 1990- 2000*	1980 - 1984 1984 - 1986 1986 - 1988 1988 – 1990 1990- 2000	

NAME – Michael J. Myers

ISOTOPES MANIPULATED	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
H^3, C^{14}		Indiana University	1980 - 1984	Drug metabolism, DNA proliferation, protein production
H^3, C^{14}, P^{32}, I^{125}		Medical College of Virginia	1984 - 1986	DNA proliferation, DNA labeling, protein labeling, protein production
H^3, C^{14}, P^{32}, I^{125}		University of Illinois	1986 - 1988	DNA proliferation, DNA labeling, protein labeling, protein production
H^3, C^{14}		NIH	1988 - 1990	Drug metabolism, DNA proliferation
H^3		FDA	1990 - ~1996	DNA proliferation

CURRICULUM VITAE 2015

Myers, Michael J.

US FDA/Center for Veterinary Medicine
8401 Muirkirk Road
Laurel, MD 20708
(301)-210-4355
michael.myers@fda.hhs.gov

1. Educational Background:

[redacted]: Purdue University, Indianapolis, Indiana; major, Biology; B.S. [redacted]

[redacted] Indiana University, I.U. School of Medicine, Indianapolis, Indiana; major, Pharmacology; minor, Immunology. Ph.D., [redacted]

2. Additional Educational Training:

   a. Postdoctoral Research Associate, Dept. of Animal Sciences, University of Illinois. Postgraduate training in Immunology and Immunotoxicology [redacted]

   b. Postdoctoral Fellow, Dept. Microbiology & Immunology, Medical College of Virginia. Postgraduate training in Immunotoxicology, [redacted]

3. Professional Experience:

Sept 2010- Present, Senior Biomedical Research Pharmacologist, Division of Applied Veterinary Research, Center for Veterinary Medicine, US FDA.

July 1992 – Sept 2010, Research Pharmacologist, Division of Animal Research, Center for Veterinary Medicine, US FDA.

July-Nov 2009, Acting Director, Division of Animal Research

March-Dec 1999, Acting Director, Division of Animal and Food Microbiology

March 1995 - 2002, Affiliate Member of Graduate Faculty, Department of Veterinary Physiology, Pharmacology and Toxicology, Louisiana State University.

February 1993 - July 1993, Acting Supervisory Research Pharmacologist, Pharmacology and Biochemistry Branch, Division of Animal Research, Center for Veterinary Medicine, US FDA.

Sept 1990 - July 1992, Research Pharmacologist, Veterinary Pharmacology and Toxicology, Division of Veterinary Medical Research, Center for Veterinary Medicine, US FDA.

October 1988 - 1990, Senior Staff Fellow, NIH, NCI, DCE, Laboratory of Molecular Carcinogenesis, Bethesda, Maryland.

1987 - 1988, Visiting Assistant Professor, Department of Animal Sciences, University of Illinois, Urbana, Illinois.

4. Honors and Awards:

Member, Sigma Xi

Co-Investigator on an NIH/NIEHS funded grant, "Dimethylnitrosamine Effects on Cellular Immunity", funded for 8/1/87 through 7/31/92.

1997, Recipient, CVM Excellence in Science; Research Scientist of the Year Award.

Co-Investigator on an FDA Office of Science funded grant "Emergence of Antibiotic Resistance: Roles of Mutator Pathogens"

1999, Recipient, FDA Commendable Service Award, member of the CVM Food Safety Initiative Group.

1999, Recipient, FDA Group Recognition Award, member of the CVM Fluoroquinolone Risk Assessment Working Group.

2000, Recipient, FDA Scientific Achievement Award: Outstanding Inter Center Scientific Collaboration

2004, Recipient, CVM Team Excellence Award, member of the CVM Animal Drug. Biological Working Group

2005, Recipient, FDA Commissioner's Special Citation Award: BSE Rapid Test Kit Evaluation Team.

2005, Recipient, FDA Leveraging/Collaboration Award: BSE Import Sampling Team.

2005, Recipient, FDA Scientific Achievement Award: Outstanding Inter Center Scientific Collaboration.

2008, Recipient, FDA Group Recognition Award: CVM Office of Research Institutional Animal Care and Use Committee.

2009, Recipient, Team Excellence Award, P-glycoprotein Safety Research Team.

2009, Recipient, FDA Outstanding Service Award.

2011, Recipient, FDA Team Excellence Award, ProHeart RiskMAP Working Group.

2001, Recipient, FDA Group Recognition Award, AAVPT Veterinary Drug Life Cycle Course Committee.

2012, Recipient, FDA Group Recognition Award, Bad Bug Book Chapter (on BSE), (CFSAN citation).

2013, Recipient, FDA Group Recognition Award, Stem Cell Research Group.

2015, Recipient, FDA Group Recognition Award, Agency Cross-Cutting, Human Food Safety – Arsenic in Poultry Feed Working Group.

2015, Recipient, FDA Group Recognition Award, Agency Cross-Cutting, Stem Cell Technology Team

2015, Recipient, FDA Group Award, Non-Agency Cross-Cutting, ProTech (Glycolated Protein Tech Team).

2015, Recipient, FDA Group Award, Non-Agency Cross-Cutting, Cell-Based Products Guidance Working Group

5. Special Invitations:

Invited Seminars:

a. Indiana State University Department of Biology,; Terre Haute, Indiana. "Alterations in Cellular Immunity Following In Vivo Exposure to the Liver Toxicant Dimethylnitrosamine," 1987.

b. National Institutes of Environmental Health Sciences, Immunotoxicology Section; Research Triangle Park, North Carolina. "Dimethylnitrosamine-Induced Alterations in Cell Mediated Immunity," 1987.

c. Purdue University, Department of Veterinary Physiology & Pharmacology; West Lafayette, Indiana. "Alterations in Cell Mediated Immunity Following In Vivo Exposure to Dimethylnitrosamine", 1987.

d. Louisiana State University Department of Veterinary Physiology, Pharmacology and Toxicology,. "Cytokines and cytokine-induced changes in metabolism: Applications of Biomedical Research to Agriculture," February 24, 1995.

e. University of Maryland, VA-MD Regional College of Veterinary Medicine. "Influence of Pulmonary Infection or Endotoxemia on the Pharmacokinetics of Enrofloxacin in Swine." May 5, 1999.

f. Kansas State University, College of veterinary Medicine, Department of Anatomy and Physiology. "Pleuropneumonia, Inflammation, and Dexamethasone: Interactions and Impact on the Pharmacokinetics of Enrofloxacin in Swine." April 9, 2001.

g. 2002 Annual Meeting of the Association of Southern Feed, Fertilizer and Pesticide Control Officials. "Development of Novel Methods for the Detection of Prohibited Materials in Animal Feed and Feed Ingredients." June 18, 2002.

h. USDA-ARS Workshop on TSE Research. Albany CA. "TSE Research at FDA" July 12, 2002.

i. 2002 Annual meeting of the International Society for the Study of Xenobiotics, Symposium 15; Orlando FL "Human, Pig and Minipig Cytochrome P450: Why Men Are Not Pigs Are Not Minipigs." Oct 30, 2002.

j. 2003 Mid Year AAFCO meeting workshop *Detection of Animal Proteins Prohibited in Ruminant Feed: A Key Tool for Prevention of Bovine Spongiform Encephalophathy (BSE)* "Novel Approaches and Probes for PCR Detection of Animal Derived Materials." Jan 17, 2003.

k. 2003 Mid Year AAFCO meeting workshop *Detection of Animal Proteins Prohibited in Ruminant Feed: A Key Tool for Prevention of Bovine Spongiform Encephalophathy (BSE)* "Immunochemical Detection of Prohibited Proteins." Jan 17, 2003.

l. BIO2004 Annual International Convention; San Francisco, CA. "Detection of Prohibited Animal Proteins: Tools in Preventing the Spread of BSE." June 7, 2004.

m. Nucleic Acid-Based Technologies 2004: Applications Amplified "Development of PCR-Based Assays to Detect Animal-Derived Materials in Animal Feed." June 22, 2004.

n. University of Maryland, Department of Animal and Avian Sciences, "Detection of BSE and Animal Proteins in Animal Feed," May 11, 2005.

o. Annual Meeting, Association of Southern Feed, Fertilizer, and Pest Control Officials Analytical. "Methods to Detect Processed Animal Proteins: Past, Present and Future," June 21, 2005.

p. Annual Meeting, American Oil Chemists Society, "Development and Validation of PCR-Based Methods for the Detection of Animal Proteins in Animal Feed." May 1, 2006.

q. 2006 Annual Meeting, American Oil Chemists Society, "Evaluation of Commercial Test Kits Marketed for the Detection of Animal Proteins in Animal Feed. May 1, 2006.

r. Howard University, Department of Microbiology, "From Pharmacology to Feed: What a Long, Strange Trip," February 22, 2007.

s. Center for Food Safety & Applied Nutrition, Office of Applied Research & Safety Assessments, "Enforcement of the 1997 Feed Ban: Development, Evaluation and Validation of Analytical Methods," July 15, 2010.

t. Center for Veterinary Medicine, "Identification and Application of Biomarkers in Veterinary Medicine," September 23, 2014.

Invited Books and Book Chapters:

a. Schook, L. B. and M. J. Myers. (1994) Tissue macrophages: Nitrosamines. In: Xenobiotic Induced Inflammation: Role of Cytokines and Growth Factors. (ED. L. B. Schook and D. L. Laskin) Academic Press, Inc., Orlando, FL. pp 173-192.

b. Cavagnaro, J., Mielach, F. A., and Myers, M. J. (1995) Predictive value of immunotoxicological evaluation of therapeutic products: assessment of safety. In: Methods in Immunotoxicology. (ED. G. R. Burleson, J. H. Dean, & A. E. Munson). Wiley-Liss, Inc., New York, NY. pp 37-49.

c. Myers, M. J., and Schook, L. B. (1995) Immunotoxicity of N-Nitrosamines. In: Experimental Immunotoxicology. (ED. R. Smialowicz and M. P. Holsapple) CRC Press, Boca Raton, FL, 343-358.

d. Cytokines in Animal Health and Disease. (1995) (ED. M. J. Myers and M. P. Murtaugh). Marcel-Dekker.

e. Myers, Michael J. (2005) Detecting animal tissues in feed and feed ingredients. In: Improving the Safety of Fresh Meat. (ED. J. N. Sofos). CRC Press, Woodhead Publishing Ltd, Cambridge, England, pp56-76.

Invited Lectureships:

a. Instructor for course "Hybridoma Workshop," 1986, Medical College of Virginia.

b. Lecturer for the Immunophysiology graduate course. 1987, Department of Animal Sciences, University of Illinois.

6. TEACHING EXPERIENCE:

Fall 1980,	Lecturer, Nursing Pharmacology
Fall 1981,	Lecturer, Respiratory Therapy Pharmacology
1981-1983,	Graduate Laboratory Teaching Assistant; Medical Pharmacology
1982-1983,	Laboratory Instructor; Introductory Zoology
Fall 1985,	Laboratory Instructor; Medical Microbiology and Immunology

7. Graduate Student Committees and Students Supervised:

Ph.D. Research Advisor:

Hala Awney, University of Alexandria, Egypt, Department of Environmental Studies, Graduated [redacted]

Lynn Post, Louisiana State University, Department of Veterinary Physiology, Pharmacology and Toxicology, [redacted], graduated, Ph.D.

Sharla Peters, Howard University, Department of Microbiology; [redacted] graduated, Ph.D.

Trevon Swain, University of Maryland, Department of Biochemistry; Ph.D. Candidacy, [redacted]

Masters Research Advisor

Polly Anne Glover, Virginia Polytechnic Institute and State University, Department of Biomedical Sciences and PathoBiology, [redacted]

Christine Deaver, Howard University, Department of Biology, [redacted]

Ph.D. Research Committee Member:

Robert Hunter, Louisiana State University, Department of Veterinary Physiology, Pharmacology and Toxicology, 1996-1999.

Undergraduate/Graduate Students Supervised:

Matthew Landry, Virginia Polytechnical Institute, Pre-veterinary Summer Intern, [redacted]
Douglas Palmer, St. Mary's College, Summer intern, [redacted] and [redacted]
Okunola Oladotum, Howard University, CVM Summer Intern Program, [redacted].
Haile Yancy, Howard University, CVM Summer Intern Program, [redacted].
Magalie Emile, Howard University, CVM Summer Intern Program, [redacted]
Allison Bowden, James Madison University, CVM Summer Intern Program, [redacted]
Jacquline Mason, Howard University, CVM Summer Intern Program, [redacted]
Adrianne Stephenson, Florida State A & M University, CVM Summer Intern Program, [redacted]
Shonette Grant, Claflin University, CVM Summer Intern Program, [redacted]
Heidi Swaim, St. Mary's College, Student Volunteer, [redacted]
Katherine Shull, Indiana Wesleyan College, Summer Intern, [redacted].
Grayson Wallace, U. of Georgia, College of Veterinary Medicine, Summer Intern, [redacted]
Maggie Prescott, University of New Hampshire, CVM Summer Intern Program, [redacted]
Megan Walker, Lubbock Christian University, Summer [redacted]
Edith Blair, University of Maryland, CVM Summer Intern Program, [redacted]
Nicholas Millington, University of Maryland, CVM Summer Intern Program, [redacted]

High School Summer Interns Supervised:

Paige Mossman, Laurel High School, [redacted]
Anuja Mohla, Laurel High School, [redacted]

8. Membership in Professional or Honorary Societies:

American Association of Immunologists, elected, 1990-present
Society of Toxicology, elected, 1987-1996.
American Association for the Advancement of Science, honorary.

9. Offices, Committee Assignments or Special Assignments held in Professional and Honorary Societies:

Member:	Research Awards Committee for the Immunotoxicology Specialty Section of the Society of Toxicology, 1992.
Member:	Regulatory Affairs Committee for the Immunotoxicology Specialty Section of the Society of Toxicology, 1992.
Member:	USDA/CSRS/NRC Grant Review Panel "Identifying Genetic Mechanisms and Gene Mapping", 1994

Ad Hoc Reviewer: USDA/CSRS/NRC Grant Review Panel "Identifying Genetic Mechanisms and Gene Mapping," 1995-2002.

Ad Hoc Reviewer: USDA/CSRS/NRC Grant Review Panel "Animal Health and Well-being/Animal Virology and Viral Immunology" 1995-2002.

Ad Hoc Reviewer: USDA/CSREES/NRICGP Grant Review Panel "Ensuring Food Safety Program," 1999-2002.

Ad hoc Reviewer — USDA Office of Science Quality Review Panel, Immunology programs, National Program 108 Action Plan on Food Safety. 2000.

Member: — US FDA/CFSAN Food Safety and Security Research Grant Review Panel "Rapid Methods Development" August, 2003.

Ad hoc Reviewer — USDA/CREES Small Business Innovation Research Program, Animal Production and Protection, 2007.

Reviewer — FDA Chief Scientist Challenge Grant Review, 2015

10. Outside Professional Advisory and Consulting Activities:

1988, Ad hoc Reviewer in field of cellular immunology for Journal of Leukocyte Biology.
1990. Ad hoc Reviewer in area of cellular immunology for the journal Experimental Cell Research.
1992. Ad hoc Reviewer in the area of immunopharmacology for the journal Immunopharmacology.
1993, Ad hoc Reviewer in the area of veterinary cytokines for the journal Veterinary Immunology and Immunopathology.
1996. Ad hoc Reviewed the book "Development of Veterinary Dosage Forms" for Marcel-Dekker, Inc.
1997. Ad hoc Reviewer in the area of humor immunity for The European Journal of Epidemiology.
2000. Ad hoc Reviewer for Anaerobe in the area of humor immunity.
2000. Ad hoc reviewer for Clinical and Laboratory Diagnostic Immunology in area of immunochemistry.
2001-present: Reviewer: American Journal for Veterinary Research, and Journal of the American Veterinary Medical Association.
2002. Ad Hoc Reviewer: Journal of Agricultural Chemistry and Food & Chemical Toxicology: PCR methods for detection of animal material in animal feed (3 papers in toto).
2003. Ad Hoc Reviewer: Molecular and Cellular Probes: PCR methods for detection of animal material in animal feed.

2004. Ad hoc Reviewer: Journal of Agriculture and Food Chemistry: PCR methods for detection of animal proteins in human food.
2004 Ad Hoc Reviewer: Journal of the American Veterinary Medical Association: Pharmacology.
2004. Ad Hoc Reviewer: Current Pharmaceutical Design: Swine P450 review
2004. Ad Hoc Reviewer: Life Science; immunopharmacology.
2005. Ad Hoc Reviewer: Journal of Zoo and Wildlife Medicine; pharmacokinetics
2006. Reviewer, Biochemical Pharmacology
2006. Reviewer, Food Control
2007. Reviewer, Biochemical Pharmacology (1), Journal of Food Protection (3), Journal of Agriculture and Food Chemistry (1) & Food Control (1)
2008. Reviewer, Journal of Food Protection, Journal of Agriculture and Food Chemistry, Drug Metabolism Letters, American Journal of Veterinary Research, Pakistan Journal of Scientific and Industrial Research, Trends in Food Science, Food Control.
2009. Reviewer, American Journal of Veterinary Research, Journal of Food Protection
2010. Reviewer, Journal of Pharmacy & Pharmacology, Journal of Food Protection, The Veterinary Journal, & International Journal of Interferon, Cytokine and Mediator Research.
2011. Reviewer, Journal of Xenobiotics; Food Science & Technology, Journal of Food Protection, Journal of Agriculture and Food Chemistry, The Veterinary Journal
2012. Reviewer, The Veterinary Journal, Journal of Food Protection, Journal of Agriculture and Food Chemistry, American Journal of Veterinary Research
2013. Reviewer, The Veterinary Journal, Journal of Food Protection, Food and Chemical Toxicology, The World Science Journal
2014. Reviewer, The Veterinary Journal, Food and Chemical Toxicology, Journal of Zoo and Wildlife Medicine, Journal of Pharmacy and Pharmacology
2015. Reviewer, The Veterinary Journal, Food and Chemical Toxicology, Journal of Zoo and Wildlife Medicine, Journal of Pharmacy and Pharmacology, Journal of the Association of Official Analytical Chemists International

11. FDA Special Assignments and Advisory Activities:

a. 1990 - 2012. Written numerous consultive reviews for the Office of New Animal Drugs in support of the review process for New Animal Drug Applications. These reviews consisted of evaluating target animal safety and efficacy for potential immunomodulatory drugs or drugs with the potential to alter the immune system, reviewing safety data, the potential impact on human food safety, and potential immunotoxicity of new animal drugs. The Target Animal Safety reviews were conducted for drugs to be used in either food animals or companion animals. The Target Animal Safety reviews also necessitate meeting with the sponsors to discuss protocols, along with writing and reviewing FOI summaries and package labeling for new animal drugs.

b. Advisor to MOU committee on cytokines and immunomodulators.
c. Member of standing committee with USDA/APHIS and CVM on jurisdiction of novel products; member of committee drafted new MOU on jurisdiction of novel products.
d. Division representative to the Center's Animal Welfare Committee
e. Member, Animal Welfare Guidelines Subcommittee; the purpose was to develop written guidelines for the Center.
f. Expert Witness for FDA in a Federal drug seizure trial involving colostrum-based products; November 1993.
g. Member, FDA Immunology Workshop Planning Committee, 1995.
h. Member, FDA InterCenter Committee for Immunotoxicology, 1995-2000
i. Briefed Center Director on new hypersensitivity model and its potential utility for research at CVM.
j. Chair, CVM Task Force on Veterinary Cytokines, 1995.
k. Member, Strategic Implementation Group 1.2.7, Setting Research Priorities. 1995.
l. Leadership Philosophy workgroup, March, 1997.
m. Chair, FDA/CVM Office of Research Institutional Animal Care and Use Committee, January 1997-2009.
n. Vice Chair, FDA/CVM Office of Research IACUC, Jan 2010- Dec 2010.
o. April 1997, At the request of the Center Director, reviewed literature citations which were used in support of the Center for Veterinary Medicine's ban on extralabel use of fluoroquinolones and aminoglycocides.
p. May-September, 1997, Member, CVM Fluoroquinolone Workgroup,
q. June-September 1997, Chair, CVM Fluoroquinolone Risk Assessment Workgroup
r. Member, CVM Fluoroquinolone Strategy Workgroup, 1997-1998.
s. April-July, 1997, Member, Office of Research Food Safety Initiative Planning Workgroups Chair, Antibiotic Resistance Research planning subgroup.
t. Member, CVM/Office of Research Food Safety Initiative Project Advisory Group, 1997.
u. Member, 1997 FDA Science Forum Planning Committee.
v. Member, 1998, Post-Approval Monitoring Program development workgroup for new fluoroquinoline to be used in veterinary medicine.
w. 1998, Member, FDA planning committee for a workshop on microarray technologies.
x. 1998, Member, Search Committees for two Research Microbiologists.
y. 1998, Member, Search Committee for Research Aquatic Microbiologist.
z. 1998-2006, Member, Office of Research Computer Committee. The ORCC was charged to review all computer, software and ADP needs and purchases and make recommendations. In addition, the ORCC led the Office efforts to implement 21 CFR; Part 11. Electronic Record Keeping.
aa. 2002, Member, Ad Hoc Peer Review Panel for two CDER scientists; in-depth reviewer for one of the two scientists.
bb. April 2002; Wrote review from scientific literature on probability of oral absorption of proteins for FDA's Office of Criminal Investigation
cc. October 2003; Expert witness for FDA in federal trial on the issue of oral absorption of

chicken antibodies in an egg powder for use in controlling urogenital infections.

dd. Oct 18, 2004, Presented results of prohibited materials test kit evaluation to FDA-AAFCO annual Briefing & Planning Conference.

ee. 2004-2010, provided annual updates to members of the CVM-ORA Field Committee on the ongoing status of the development and validation of analytical methods to help enforce the 1997 Feed Ban.

ff. 2006 - 2007, Member, ProHeart 6 working group.

gg. January 2007, Went to China at request of USDA to discuss with the Chinese government issues of testing animal meals imported to China from the U.S.

hh. 2007; drafted new Memorandum of Understanding between CVM and USDA/APHIS/Center for Veterinary Biologics that would provide guidance to industry on the jurisdiction of new and novel therapeutic agents for use in veterinary medicine

ii. June - Oct 2007, Lead CVM's efforts to work with the sponsor of ProHeart 6 (Fort Dodge Animal Health/Wyeth) on the design of a guinea pig allergenicity safety study for several components and contaminants of ProHeart 6. Subsequently was responsible for performing the data audit and data analysis of the results from those studies as well as presenting those findings to the ProHeart 6 working group.

jj. Feb, 2008, Expert witness for FDA in a federal trial on the issue of oral absorption of proteins from bovine colostrum by adults for cancer therapy.

kk. June, 2009, PCR training course on Real-Time PCR for animal feed/MBM for ORA analysts (3 days) and State analysts (two- 3 day sessions).

ll. Fall 2009 - Spring 2010; member Veterinary Medical Advisory Committee planning work group for ProHeart 6 discussion.

mm. Fall, 2009 – present, member Protein Technology Tech Team

nn. Spring 2010- present, Proheart 6 RISKMAP Committee

oo. Spring 2010, AAVPT Drug Approval Course Planning Committee

pp. August 23, 2010, FDA Federal-State Relations Cooperative Grant panel meeting to evaluate grant proposals.

qq. August 2010- present, Master Reviewer Committee member

rr. Jan 2010-Jan 2012, member FDA-Track review group of NCTR's research activities

ss. October, 18-20, 2010, Participant, NCTR Science Advisory Board Meeting

tt. March 4, 2011 Presentation at AAVPT Drug Approval Course

uu. June, 2011- present, Biomarkers Working Group

vv. Summer 2010- 2012, Xylitol Working Group

ww. Jan, 21, 2011- present, Immunomodulators Discussion Group

xx. September, 2011- present, Pharmaccine Tech Team

12. Competitive Research Grants
    a. Critical Path Initiative grant, "Pharmacogenomics of the MDR-1 Gene Mutation and the Effect on P-Glycoprotein Substrates in Dogs." Co-PI with Dr. Haile Yancy (CVM/OR). Source: Office of the Commissioner. (April 2008 -March 2011; $450,000).

13. Laboratory Information Bulletins

a. LIB 4486 "A Rapid Real-Time PCR Method for the Detection of Prohibited Animal Material in Feed Samples," Haile F. Yancy, Jewell D. Washington, Lauren Callahan, Jacquline A. Mason, Christine M. Deaver, Dorothy E. Farrell, Tai Ha, Eric Sespico, Daniel Falmlen, Heidi Swain, and Michael J. Myers.
b. LIB 4544 "A Rapid Multiplex Real-Time PCR Assay for the Detection of Ruminant DNA," Haile F. Yancy, Jason Ekins, Sharla M. Peters, Yolanda L. Jones, Heidi L. Swaim, Tai Ha, and Michael J. Myers.

14. CRADA's/Employee Invention Reports
    a. BioGX simplex RT-PCR beads for ruminant detection, Oligonucleotide Sequences for Simplex Real-Time Polymerase Chain Reaction Assay for the Detection of Ruminant DNA." Haile F, Yancy, Yolanda M. Jones, Michael J. Myers.
    b. BioGX multiplex RT-PCR beads for detection of ruminant and porcine materials, "Oligonucleotide Sequences for Multiplex Real-Time Polymerase Chain Reaction Assay for the Detection of Ruminant and Porcine DNA." Haile F, Yancy, Yolanda M. Jones, Sharla M. Peters, Michael J. Myers.
    c. Qiagen simplex RT-PCR primers for detection of cattle, sheep, and goat DNA. Application under development and review,

Bibliography

Ph.D. Thesis: 17-Beta Estradiol-Induced Modulation of the Immune System.

Articles:

1. Myers, Michael J., Ades, E. H., Jackson W. T. and Petersen, B. H. (1984). Possible in vivo modulation of the immune system by the leukotriene LTB4 I. Delayed suppression of cellular immunity. J Clin Lab Immunol 15:205-209.

2. Myers, Michael J. and Petersen, B. H. (1985). Estradiol induced alterations of the immune system I. Enhancement of IgM production. Int J Immunopharm 7:207-213.

3. Myers, Michael J., Butler, L. and Petersen, B. H. (1986). Estradiol induced alterations of the immune system II. Suppression of cellular immunity in the rat is not the result of direct estrogenic action. Immunopharm 11:47-55.

4. Blanton, Robert H., Lyte, M., Myers, Michael J. and Bick, P. H. (1986). Immunomodulation by polyaromatic hydrocarbons in mice and murine cells. Cancer Res 46:2735-2739.

5. Myers, Michael J., Heim, M. C., Hirsch, K. S., Queener, S. F. and Petersen, B. H. (1986). Translocatable estrogen receptors in rat splenic lymphocytes. Life Science 39(4):313-320.

6. Myers, Michael J., Pullen J. K. and Schook, L. B. (1986). Alteration of macrophage differentiation into accessory and effector cells from exposure to dimethylnitrosamine *in vivo*. Immunopharm 12(2):105-115.

7. Lyte, Mark, Blanton, R. H., Myers, Michael J. and Bick, P. H. (1987). Effect of *in vivo* administration of the environmental pollutant benzo(a)pyrene on interleukin-2 and interleukin-3 production. Int J Immunopharm 9(3):307-312.

8. Myers, Michael J., Dickens, C. S. and Schook, L. B. (1987) Alteration of macrophage anti-tumor activity and transferrin receptor expression by exposure to dimethylnitrosamine *in vivo*. Immunopharm 13:195-205.

9. Myers, Michael J., Schook, L. B and Bick, P. H. (1987). Examination of the mechanism of benzo(a)pyrene-induced immunotoxicity of antigen presentation. J Pharm Exp Ther 242:399-404.

10. Myers, Michael J. and Schook, L. B. (1987). Modification of macrophage differentiation: Dimethylnitrosamine induced alteration in the responses towards the regulatory signals controlling myelopoiesis. Int J Immunopharm 9(7):317-325.

11. Myers, Michael J., Blanton, R. H. and Bick, P. H. (1988). Inhibition of IL-2 responsiveness following exposure to benzo(a)pyrene is due to alterations in accessory cell functionality. Int J Immunopharm 10(2):177-186.

12. Blanton, Robert H., Myers, Michael J. and Bick, P. H. (1988) Modulation of immunocompetent cell populations by benzo(a)pyrene. Toxicol appl Pharm 93:267-274.

13. Myers, Michael J., Pullen, J. K., Ghildyal, N., Eustis-Turf , E. and Schook, L. B. (1989). Regulation of IL-1 and TNF-alpha expression during the differentiation of bone marrow derived macrophage. J Immunol 142(1):153-160.

14. Pullen, Jeffery K., Eustis-Turf, E., Myers, Michael J. and Schook, L. B. (1989). Regulation of Class II MHC gene expression during the differentiation of bone marrow derived macrophage. Cellular Immunology 121:398-413.

15. Myers, Michael J., Hanafin, W. P. and Schook, L. B. (1989). Augmented macrophage PGE_2 production following exposure to dimethylnitrosamine *in vivo*: Relevance to suppressed T cell responses. Immunopharmacology 18:115-124.

16. Myers, Michael J., Witsell, A. L. and Schook, L. B. (1989). Induction of serum colony stimulation activity (CSA) following dimethylnitrosamine (DMN) exposure: effects on macrophage differentiation. Immunopharmacology 18:125-134.

17. Myers, Michael J., Liu, G., Miller, H., Gelboin, H. V., Robinson, R. C., and Friedman, F. K. (1990). Synthetic peptide antigens elicit monoclonal and polyclonal antibodies to P450 IA2. Biochem. Biophys Res Comm 169(1):171-176.

18. Liu, Gao, Gelboin, H. V. and Myers, Michael J. (1991). Role of cytochrome P450 IA2 in acetanilide 4-hydroxylation as determined with cDNA expression and monoclonal antibodies. Arch. Biochem Biophys 284(2):234-242

19. Lockwood, John F., Myers, Michael J., Rutherford, M. and Schook, L. B. (1991). Transcriptional changes in macrophage TNF-α expression following dimethylnitrosamine exposure *in vivo*. Immunopharm 22:27-38.

20. Edwards, III, Carl K., Myers, Michael J., Kelly, K. E. and Schook, L. B. (1991). Enhanced macrophage anti-microbial activity following dimethylnitrosamine exposure *in vivo* is related to augmented production of reactive oxygen metabolites. Immunopharm. Immunotox 13(3):395-411.

21. Schook, Lawrence B., Lockwood, J. F., Yang, S.-D. and Myers, Michael J. (1992). Dimethylnitrosamine (DMN)-induced IL-1β, TNFα and IL-6 inflammatory cytokine expression. Tox appl Pharm 116(1):110-116.

22. Lockwood, John F., Rutherford, M., Myers, Michael J. and Schook, L. B. (1994). Induction of hepatic acute phase protein transcripts: differential effects of acute and sub-chronic dimethylnitrosamine (DMN) exposure *in vivo*. Tox appl Pharm 125(2):228-295.

23. Chaloupka, Kathy, Sanostefano, M., Goldfarb, I. S., Liu, G., Myers, Michael J., Tsyrlov, I. B., Gelboin, H. V., Krishan, V. and Safe, S. (1994). Aryl hydrocarbon (Ah) receptor-independent induction of CYP1A2 gene expression by acenaphthylene and related compounds in B6C3F1 mice. Carcinogenesis 15(12):2835-2840.

24. Myers, Michael J., Ghildyal, N. and Schook, L. B. (1995). Endotoxin and interferon-γ differentially regulate the transcriptional levels of proto-oncogenes and cytokine genes during the differentiation of CSF-1 derived macrophage. Immunology 85(2):318-324.

25. Myers, Michael J., Farrell, D. E. and M. Henderson, M. (1995). Modulation in vitro of bovine polymorphonuclear leukocytes and peripheral blood mononuclear cells by oxytetracycline. Am J Vet Res 56(8):1007-1011.

26. Myers, Michael J., Farrell, D. E. and Henderson, M. (1995). Oxytetracycline-mediated alteration of murine immunocompetence. Pathobiology 63:270-277.

27. Myers, Michael J., Farrell, D. E., Evock-Clover, C. M., Cope, C. V., Henderson, M. and Steele, N. C. (1995). Effect of recombinant growth hormone and chromium picolinate on cytokine production and growth performance in swine. Pathobiology 63:283-287.

28. Myers, Michael J. and Henderson, M. (1996). Assessment of two devices for measuring tympanic membrane temperature in swine, dairy cattle, and dairy calves. J Am Vet Medical Assoc 208(10):1700-1701.

29 Evock-Clover, Christina M., Myers, Michael J. and Steele, N. C. (1997). Effects of an endotoxin challenge on growth performance, carcass accretion rates and serum hormone and metabolite concentrations on control pigs and those treated with recombinant porcine somatotropin. J Animal Sci 75(7):1784-1790.

30. Myers, Michael J., Farrell, D. E, Evock-Clover, C. M., McDonald, M.W. and Steele, N. C. (1997) Effect of growth hormone or chromium picolinate on swine metabolism and inflammatory cytokine production after endotoxin challenge. Am J Vet Res. 58(6):594-600.

31. Myers, Michael J., Farrell, D. E., Baker, J.D., Evock-Clover, C. M. and Steele, N. C. (1999). Endotoxin challenge differentially affects cytokine production and metabolic status of growing and finishing swine. Domestic Animal Endocrinology 17(4):345-360.

32. von Bredow, J., Myers. M., Wagner D., Valdes, J., Loomis, J., Zamani, K. (2000). Agroterrorism-Agricultural infrastructure vulnerability. New York Acad Sci 894:168-180.

33. Wang R.-F., Myers, Michael J., Campbell, W., Cao, W.-W., Paine, D. and Cerniglia C.E. (2000). A rapid method for PCR detection of bovine materials in animal feedstuffs. Mol Cell Probes 14(1):1-5.

34. Myers, Michael J., Friedman, S. L., Farrell, D. E., Dove-Pettit, D. A., Bucker, M. F., Kelly, S., Madzo, S.,Warren Campbell, W., Wang, R.-F., Paine, D., Carl E. Cerniglia, C.E. (2001). Validation of a polymerase chain reaction method for the detection of rendered bovine-derived materials in feedstuffs. J Food Protection 64(4):564-566.

35. Yancy, H. F., Ayres, S., A., Farrell, D. E., Day, A., and Myers, Michael J. (2001). Differential cytokine mRNA expression in swine whole blood and PBMC cultures. Vet Immunology and Immunopathology 79(1-2):41-52.

36. Myers, Michael J., Farrell, D. E., Howard, K. D. and Kawalek, J. C. (2001). Identification of multiple constitutive and inducible cytochrome P450 enzymes in market weight swine. Drug Metabolism and Disposition 29(6):908-915.

37. Post, L. O., Cope, C. V., Farrell, D. E., Baker, J. D., and Myers, Michael J. (2002). Influence of porcine *Actinobacillus pleuropneumoniae* (APP) infection and dexamethasone on the pharmacokinetic parameters of enrofloxacin. J. Pharmcol Exp Ther 301(1): 217-222.

38. Myers, Michael J., Baarsch, M. J., and Murtaugh, M. P. (2002). Effects of pentoxifylline on inflammatory cytokine expression and acute pleuropneumonia in swine. Immunobiology 205(1):17-34.

39. Babu, U, Scott, M., Myers, Michael J., Okamura, M., Gaines, D., Yancy H. F., Lillehoj, H., Heckert, R. A., Raybourne, R. B. (2003). Effects of live attenuated and killed Salmonella vaccines on T-lymphocyte mediated immunity in laying hens. Vet Immunol and Immunopathol 91(1):39-44.

40. Post, L. O., Cope, C. V., Farrell, D. E., Baker, J. D., and Myers, Michael J. (2003). The effect of endotoxin and dexamethasone on enrofloxacin pharmacokinetics in swine. J. Pharmacol Exp Ther 304(2): 889-895.

41. Myers, Michael J., Farrell, D. E., Baker, J.D., Evock-Clover, C. M. and Steele, N. C. (2003). Long-term recombinant porcine somatotropin (PST) treatment mitigates the responses to subchronic lipopolysaccharide in swine. Domest Anim Endocrinol 24:155-170.

42. Myers, Michael J., Yancy H. F., and Farrell, D. E. (2003). Characterization of a PCR-based approach for the simultaneous detection of multiple animal-derived materials in animal feed. J. Food Protection 66(6):1085-1089.

44. Hinton, D. M., Farrell, D. E., and Myers, Michael J. (2003). Impact on cellular immunity following chronic low dose exposure to aflatoxin B1. Toxicological Sci 73: 362-377.

45. Myers, Michael J., Farrell, D. E., Palmer D. C., and Post, L. O. (2003). Inflammatory mediator production in swine following endotoxin-challenge with or without co-administration of dexamethasone. Int Immunopharm 3(4):571-579.

46. Kawalek, J. C., Howard, K. D, Farrell, D. E, Derr, J., Cope, C. V., Jackson, J., Myers, Michael J. (2003). Effect of oral administration of low doses of pentobarbital on the induction of cytochrome P450 isoforms and cytochrome P450-mediated reactions in immature Beagles. Am J Vet Res 64(9): 1167-1175.

47. Myers, Michael J., Farrell, D. E., Snider, T. G. R., and Post, L. O. (2004). Inflammatory mediators, pleuropneumonia infection and the effect of dexamethasone. Pathobiology 71(1):35-42.

48. Myers, Michael J., Farrell, D. E., Heller, D. N., Yancy, H. F. (2004). Development of a PCR-based method to identify species-specific components in dog food. Am J Vet Res 65(1):99-103.

49. Myers, Michael J., Yancy, H. F., Farrell, D. E., Washington, J. D., Frobish, R. A. (2005). Evaluation of two commercial lateral-flow test kits that detect animal proteins in animal feed. Journal of Food Protection 68(12):2656-2664.

50. Yancy, H. F., Mohla, A., Farrell, D. E., and Myers, Michael J. (2005). Evaluation of a rapid PCR-based method for detection of animal material. Journal of Food Protection 68(12):2651-2655.

51. Babu, U. S., Wiesenfeld, P. L., Raybourne, R. B., Myers, Michael J., and Gaines, D. (2005). Effect of dietary fish-meal on cell-mediated immune response of laying hens. Intl J Poultry Science. 4(9):652-656.

52. Wiesenfeld, P. L., Babu, U. S., Raybourne, R. B., Gaines, D., O'Donnell Jr, M., Myers, Michael J. (2005). Effect of increasing dietary fish-meal on plasma, liver and spleen fatty acids. Intl J Poultry Science. 4(10):728-733.

53. Myers, Michael J., Yancy, H. F., et. al. (2006). Validation of a PCR-based method for the detection of various rendered materials in feedstuffs using a forensic DNA extraction kit. Journal of Food Protection. 69(1):205-210.

54. Kawalek, J. C., Myers, Michael J., Howard, K. D., Farrell, D. E., Shaik, B. (2006). Hepatic CYP isoforms and drug metabolizing enzyme activities in broiler chicks. Intl J Poultry Science. 5(2):104-111.

55. Myers, Michael J, Yancy, H. F., Farrell, D. E., Washington, J. D., Deaver, C. M., and Frobish, R. A. (2007). Assessment of two ELISA tests marketed for detection ruminant proteins in finished feed. J Food Protection 70(3):692-699.

56. Hunter, R. P., Short, C. R., Myers, M. J., Farrell, D. E., McClure, J. R., Koch, C. E., & Keowen, M. L. (2007). The effect of cimetidine and aminoguanidine on pro-inflammatory cytokines in the horse. J Equine Vet Sci 27(7):307-312.

57. Scott, M. L. and Myers, Michael J. (2009). Development of an *ex vivo* assay for use as a surrogate model to assess the impact of endotoxin on cattle. The Professional Animal Scientist 25:60-64.

58. Yancy, H. F., Washington, J. D., Callahan, L., Mason, J. A., Deaver, C. M., Farrell, D. E., and Myers, Michael J. (2009). Development, evaluation, and peer-verification of a rapid real-time PCR method for the detection of animal material. J Food Protection. 72(11):2368-2374.

59. Myers, Michael J., Scott, M. L., Deaver, C. M., Farrell, D. E., and Yancy, H. F. (2010). Biomarkers of inflammation in cattle for determining the effectiveness of anti-inflammatory drugs. J Vet Pharmacol Ther 33:1-8.

60. Myers, Michael J., Farrell, D. E., Howard, K. D., and Kawalek, J. C. (2010). Effects of intravenous administration of lipopolysaccharide on cytochrome P450 isoforms and hepatic drug metabolizing enzymes in swine. Am J Vet Res 71(3):342-348.

61. Myers, Michael J., Farrell, D. E., Deaver, C.M., Mason, J., Swaim, H. L., Yancy, H. F. (2010). Detection of rendered meat meals by PCR is dependent on animal species of origin and DNA extraction method. J Food Protection 73(6):1090-1096.

62. Peters, S., Yancy, H. F., Bremer, E., Monroe J., Paul D., Stubs J., Myers, Michael J. (2011). *In vitro* identification and verification of gene-based inflammatory biomarkers in swine. Veterinary Immunology & Immunopathology 139(1):67-72.

63. Orzechowski, K. L., Swain, M. D., Robl, M. G., Tinaza, C. A., Swaim, H. L., Jones, Y. L., Myers, Michael J., Yancy, H. F. (2012). Neurotoxic effects of ivermectin administration in genetically engineered mice with targeted insertion of the mutated canine ABCB1 gene. Am J Vet Res 73(9):1477-1484.

64. Ekins, J., Peters, S. M., Jones, Y. L., Swaim, H., Ha, T., Myers, Michael J., Yancy, H. F. (2012). Validation of a multiplex real-time PCR assay for the detection of ruminant material. J Food Protection 75(6):1107-1112.

65. Kenyon, E. A., Peters, S. M., Jones Y. L., Deaver, C. M., Myers, Michael J., Yancy, H. F. (2012). *In vitro* characterization of biomarkers across species. J Advanced Veterinary Research 2:80-85.

66. Peters, S. M., Yancy, H.F., Deaver, C.M., Jones, Y.L., Kenyon, E., Chiesa, O.A., Esparza, J., Screven, R., Stubbs III, J.T., Lancaster, V., Yang, M., Wiesenfeld P.L., & Michael J. Myers. (2012). *In vivo* characterization of inflammatory biomarkers in swine and the impact of flunixin meglumine administration. Veterinary Immunology & Immunopathology 148(3):236-242.

67. Swain, M. D., Orzechowski, K.L., Swaim, H. L., Jones, Y. L., Robl, M. G., Tinaza, C. A., Michael J. Myers, Jhingory, M. V., Buckely, L. E., Lancaster, V. A., Yancy, H. F. (2013). P-gp substrate-induced neurotoxicity in an ABC B1a Knock-in/ABCB1b Knock-out mouse model with a mutated canine ABCB1 targeted insertion. Research in Veterinary Science 94(3): 656-661.

68. Martinez, M., Antonovic, L., Court, M., Dacasto, M., Fink-Gremmels, J., Kukanich, B., Locuson, C., Mealey, K. L., Michael J. Myers, Trepanier, L. (2013). Challenges in exploring the cytochrome P450 system as a source of variation in canine drug pharmacokinetics. Drug Metabolism Reviews. 45(2):218-230.

69. Screven, R., Kenyon, E., Myers, Michael J., Yancy, H. F., Skasko, M., Boxer, L., Bigley III, E. C., Borjesson, D. L., Zhu, M., (2014). Immunophenotype and PCR array gene expression profile of mesenchymal stem cells derived from canine adipose tissue and bone marrow. Veterinary Immunology & Immunopathology 161(1 & 2):21-31.

70. Zhu, M., Ming, Y., Swaim, H., Swain, M. D., Myers, Michael J., Deaver, C., Wu, X., Jones, Y. L., & Yancy, H. F. 2014. Identification of potential biomarkers of P-glycoprotein substrate neurotoxicity in transgenic mice expressing the mutated canine ABCB1 gene. Am J Vet Res 75(12):1104-1110.

71. Zhu, M., Yancy, H. F., Deaver, C., Jones, Y., L., and Myers, Michael J. 2015. Loperamide-induced immune and inflammatory responses in Collies with ABCB1-1Δ mutation associated with ivermectin sensitivity. Journal of Veterinary Pharmacology & Therapeutics (in print).

72. Myers, Michael J., Martinez, M., Li, H., Qui, J., Troutman, L., Sharkey, M, and Yancy, H.F. 2015. Influence of ABCB1 genotype in Collies on loperamide pharmacokinetics and pharmacodynamics in a dose-escalation study. Drug Metabolism and Disposition. 43:1392- 1407.

Commissioned Guest Editorials

1. Myers. M. J. 2011. Molecular Identification of Animal Species in Food: Transition from Research Laboratories to the Regulatory Laboratories. The Veterinary Journal 90:7-8.

Book Chapters

1. Schook, L. B., Pullen, J. K., Myers, Michael J., Eustis-Turf, E. and Wang, X.-M. (1987). Regulation of MHC and Interleukin-1 gene transcription in differentiating macrophage. In: Progress in Leukocyte Biology Vol.7, Major Histocompatibility Genes and Their Role in Immune Function. (ED. C. S. David) Plenum Publishing Co. p 283-296.

2. Eustis-Turf, E., Pullen, J. K., Myers, Michael J., Wang, X.-M. and Schook, L. B. (1987). Regulation of class II MHC gene expression during macrophage differentiation. In Antigen Presenting Cells: Diversity, Differentiation and Regulation. (Ed. L. B. Schook and J. G. Tew) Alan R. Liss, Inc., New York, NY p 169-180.

3. Awney, H.. Mostafa, M. H. and Myers, Michael J. (1992) Cytochrome P450 (P450) mediated H_2O_2 production and its role in mutagenesis. In: Oxidative Damage and Repair: Clinical, Biological and Medical Aspects. (ED. Kelvin J. A. Davies) Pergamon Press, Inc., Elmsford, NY p 742-746.

4. Schook, L. B. and Myers, Michael J. (1994). Tissue macrophages: Nitrosamines. In: Xenobiotic Induced Inflammation: Role of Cytokines and Growth Factors. (ED. L. B. Schook and D. L. Laskin) Academic Press, Inc., Orlando, FL. pp 173-192.

5. Cavagnaro, J., Mielach, F. A., and Myers, Michael J. (1995). Predictive value of immunotoxicological evaluation of therapeutic products: assessment of safety. In: Methods in Immunotoxicology. (ED. G. R. Burleson, J. H. Dean, & A. E. Munson). Wiley-Liss, Inc., New York, NY. pp 37-49.

6. Myers, Michael J., and Schook, L. B. (1995). Immunotoxicity of N-Nitrosamines. In: Experimental Immunotoxicology. (ED. R. Smialowicz and M. P. Holsapple) CRC Press,

Boca Raton, FL, 343-358.

7. Myers, Michael J. and Kawalek, J. C.. (1995). Effect of cytokines on drug metabolizing enzymes. In: Cytokines in Animal Health and Disease. (ED. M. J. Myers and M. P. Murtaugh). Marcel-Dekker, New York, NY, pp 235-259.

8. Myers, Michael J. and Murtaugh, M. P. (1995). Biology of tumor necrosis factor. In: Cytokines in Animal Health and Disease. (ED. M. J. Myers and M. P. Murtaugh). Marcel-Dekker, New York, NY, pp 121-151.

9. Murtaugh, M. P. and Myers, Michael J. (1995). Future directions in animal cytokine research and applications. In: Cytokines in Animal Health and Disease. (ED. M. J. Myers and M. P. Murtaugh). Marcel-Dekker, New York, NY, pp 447-445.

10. Myers, Michael J. (2005). Detecting animal tissues in feed and feed ingredients. In: Improving the Safety of Fresh Meat. (ED. J. N. Sofos). CRC Press, Woodhead Publishing Ltd, Cambridge, England, pp56-76.

11. Myers, Michael J. (2012). Prions and Transmissible Spongiform Encephalopathies. In: Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook. 2nd Edition. Pp 170-174. Published on line at: http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm.

Books Edited

1. Cytokines in Animal Health and Disease. 1995. Editors: Michael J. Myers and Michael P. Murtaugh. Marcel-Dekker 1995.

Articles in Lay Publications or Non-Peer Reviewed Journals

1. Myers, Michael J. New method available for detection of bovine material in feed. FDA Veterinarian. Vol 13(2), March/April 1998 pp1-3.

2. Myers, Michael J. CVM scientists develop PCR test to determine source of animal products in feed, pet food. FDA Veterinarian. Vol 19(1), Jan/Feb 2004 pp8-11.

3. Myers, Michael J. CVM's Office of Research Develops New PCR-Based Method for Testing Animal Feed. FDA Veterinarian Vol 25(1), 2010.

Manuscripts Submitted for Publication

1. Chiesa, O. A., Heller, D. N., Wallace, G., Karanian, J. W., Pritchard, W. F., Lopez, M., Smith, S., Kijak, P. J., Ward, J. L., von Bredow, J., and Myers, Michael J. Inhalation anesthesia induced by isofluorane alters penicillin disposition in swine tissues.

2. Kawalek, J. C., Howard, K. D., Jones, Y., Scott, M. L., and Myers, Michael J. Depletion of florfenicol in lactating dairy cows after intramammary and subcutaneous administration as Nuflor®.

Manuscripts in Preparation:

1. Deaver, C. M., Screven, R., Yancy, H. F., Myers, Michael J. Molecular characterization of a novel *in vitro* model of inflammation; Identification of common pathways and mechanism of action.

2. Deaver, C. M., Screven, R., Yancy, H. F., Myers, Michael J. Identifying genomic and protein biomarkers associated with pain using a porcine *in vitro* model of inflammation.

3. Johnson, A., Myers, Michael J. Non-steroidal anti-inflammatory drugs alter inflammatory responses through Nuclear Factor- κβ in a cyclooxygenase-independent manner.

4. Zhu, M., Screven, R., Yancy, H. F., Boxer, L., Skasko, M, Bigley III, E. C., Borjesson, D. L., Myers, Michael J. Gene expression profiles of equine mesenchymal stem cells derived from multiple tissue types and cross-species comparison to canine mesenchymal stem cells.

5. Devireddy, L., Myers, Michael J., Boxer, L., Bauer, S. Stem cell based therapies in veterinary clinical practice: a precarious path to success

6. Pritchard, W.F., Baker, M.W., Karanian, J. W., Chiesa, O.A., Schwartz, S., Myers, Michael. J. Pharmacoimaging of local drug delivery with quantitative computed tomography of lanthanide chelates and tissue assay

Abstracts:

1. Myers, Michael J. and Petersen, B.H. Effect of 17-beta-estradiol on the immune system of the rat. Fed. Proc. 41:587, 1982.

2. Myers, Michael J., and Petersen, B.H. Cellular immune responses in rat treated with 17-beta-estradiol. Fed. Proc. 42:713, 1983.

3. Henry, D.P., Bowsher, R.R., Myers, Michael J., Zerbe, R.L., and Petersen, B.H. Immunochemical localization of histamine-N-methyl transferase in rat kidney. Fed. Proc. 42:709, 1983.

4. Myers, Michael J., Heim, M.C., Hirsch, K.S., Petersen, B.H. Evidence for the presence of estrogen receptors in rat and human lymphocytes. Fed. Proc. 43(6):1611, 1984.

5. Myers, Michael J., Lyte, M., Bick, P.H. Cellular targets of benzo(a)pyrene-induced immunosuppression. The Toxicologist 5:45, 1985.

6. Myers, Michael J., Schook, L. B., Bick, P.H. Benzo(a)pyrene-induced down-regulation of interleukin-2 responsiveness. The Toxicologist 6:166, 1986.

7. Myers, Michael J., Dickens, C.S., Schook, L.B. Modulation of interleukin production by dimethylnitrosamine. The Toxicologist 6:166, 1986.

8. Lyte, M., Myers, Michael J., Bick, P.H. Benzo(a)pyrene-induced modulation of interleukin-1, 2 and 3 production. The Toxicologist 6:166, 1986

9. Blanton, R.H., Myers, Michael J., Bick, P.H. Definition of cellular targets of benzo(a)pyrene immunotoxicity. The Toxicologist 6:166, 1986.

10. Dickens, C.B., Myers, Michael J., Schook, L.B. Studies on macrophage transferrin receptor expression and tumoristatic activity. The Toxicologist 6:66, 1986.
11. Pullen, J.K., Myers, Michael J., and Schook, L.B. Regulation of MHC class II, tumor necrosis factor, and interleukin-1 gene transcription during the differentiation of bone marrow derived macrophages. Fed. Proc. 46:941, 1987

12. Lockwood, J.F., Myers, Michael J. and Schook, L.B. *In vitro* PGE_2 production by endotoxin and interferon-gamma stimulated macrophage. 1987 Midwest Immunology Conference.

13. Myers, Michael J., Pullen, J.K., Eustis-Turf, E. and Schook, L.B. Regulation of IL-1 and TNF-α gene expression during the differentiation of bone marrow derived macrophage (BMDM). 1987 Midwest Immunology Conference.

14. Lockwood, J.F., Myers, Michael J., and Schook, L.B. Dimethylnitrosamine (DMN)-induced changes in TNF-α expression as detected by Northern Blot Analysis. The Toxicologist 8:149, 1988.

15. Lockwood, J.F., Myers, Michael J. and Schook, L.B. Alteration of TNF-α and PGE_2 production in macrophage (MPH) following exposure to dimethylnitrosamine (DMN) *in vivo*. FASEB J. 2(4):699, 1988.

16. Ghildyal, N., Myers, Michael J., Pullen, J.K. and Schook, L.B. Expression of c-*myc*, c-*fos* and c-*fms* following endotoxin stimulation of CSF-1 induced macrophage (MPH) differentiation. 1988 Midwest Immunology Conference.

17. Ghildyal, N., Myers, Michael J., Pullen, J.K. and Schook, L.B. Expression of c-MYC, c-FOS and c-FMS following endotoxin induction of CSF-1 induced macrophage (MPH) differentiation. J. Leukocyte Biology 44(4):269, 1988.

18. Myers, Michael J., Edwards, C.K., Lockwood, J.F., Kelley, K.E. and Schook, L.B. Changes in the production of macrophage reactive oxygen intermediates (ROI) following dimethylnitrosamine exposure. The Toxicologist 9:39, 1989.

19. Lockwood, J.F., Myers, Michael J. and Schook, L.B. Induction of serum colony stimulating activity (CSA) following dimethylnitrosamine (DMN) exposure. The Toxicologist 9:18, 1989.

20. Ghildyal, N., Myers, Michael J., Pullen, J.K., Lockwood, J.F. and Schook, L.B. Regulation of proto-oncogenes during CSF-1 induced macrophage differentiation. FASEB J. 3:A1105, 1989.

21. Lockwood, J. F., Myers, Michael J., Yang, S.-D., and Schook, L. B. Inflammatory cytokine and molecular changes associated with DMN induced immune alterations. The Toxicologist 11:165, 1991.

22. Myers, M. J., Farrell, D. E., and Henderson, M. Effect of oxytetracycline (OTC) on select aspects of neutrophil (PMN) immunobiology. The Toxicologist 13:419, 1993.

23. Farrell, D., Myers, Michael J., and Hinton, D. M. Evaluation of the miniature swine for use in immunotoxicity assessment. The Toxicologist 13:326, 1993.

24. Myers, M. J., Farrell, D. E., and Henderson, M. Oxytetracycline (OTC) induced suppression of bovine and murine mononuclear cell functions. J. of Immunology 150(8):132A, 1993.

25. Myers, M. J., Farrell, D. E., Evock-Clover, C.M., Cope, C.V., Henderson, M.,and Steele, N. C. Endotoxin-induced changes in blood glucose, TNF-α and IL-6 in domestic swine. FASEB J. 8(4):A222, 1994.

26. Myers, M. J., Farrell, D. E., Evock-Clover, C.M., and Steele, N. C. Growth hormone or chromium picolinate alter swine metabolism and cytokine production following endotoxin challenge. Proceedings of the 9th International Congress of Immunology. 9:419, 1995.

27. Myers, Michael J., Farrell, D. E., Howard, K. D., and Kawalek, J. C. Identification of Swine Cytochrome P450 Isozymes. Joint AAI/ASBMB Meeting. FASEB J. 10(6), A1498, 1996.

28. Evock-Clover, C. M., Eastridge, J. S., Steele, N.C., Solomon, M. B., and Myers, M. J. Specific muscle responses to somatotropin (PST)-and endotoxin (ENDO)-induced hypertrophy and atrophy in the growing pig. J Animal Sci 74(suppl 1):143, 1996.

29. Post, L.O., Cope, C.V., Farrell, D.E., and Myers, Michael J. The effect of pulmonary infection with *Actinobacillus pleuropneumoniae* (APP) and dexamethasone on enrofloxacin pharmacokinetics in swine. FDA Forum On Regulatory Sciences, 1996.

30. Myers, Michael J., Farrell, D. E. Howard, K. D., and Kawalek, J. C. Effect of endotoxin challenge on phase 1 drug metabolizing enzymes in growing and finishing swine. FDA Forum on Regulatory Sciences, 1996.

31. Myers, Michael J., Farrell, D. E. Howard, K. D., and Kawalek, J. C. Identification and characterization of constitutive and inducible swine cytochrome P450 isozymes. FDA Forum on Regulatory Sciences, 1996.

32. Post, L.O., Cope, C.V., Farrell, D.E., Baker, J.D., and Myers, Michael J. The impact of pleural *Actinobacillus pleuropneumoniae* (APP) infection and dexamethasone, alone or in combination, on enrofloxacin pharmacokinetics in swine. FASEB J 12: 536, 1998.

33. Hunter, R.P., Short, C. R., Myers, Michael J., Farrell, D. E., McClure, J. R., Koch, C. E., and Keowen M. L. Does cimetidine have anti-inflammatory properties in a soft tissue inflammation model in the horse? Amer Assoc Vet Pharmacol and Ther 1998 Annual meeting.

34. Myers, Michael J., Farrell, D. E. Howard, K. D., and Kawalek, J. C. Alteration of constitutive cytochrome P450 activies in endotoxemic growing and finishing swine. FASEB J. 13:A814, 1999.

35. Post, L.O., Cope, C.V., Farrell, D.E., Baker, J.D., and Myers, Michael J. The effect of systemic endotoxin challenge and dexamethasone, alone or in combination, on enrofloxacin pharmacokinetics in swine. FASEB J. 13:A814, 1999.

36. Yancy, H., Ayres, S. A. Day, A., and Myers, Michael J. Differential cytokine mRNA expression in swine whole blood and PBMC cultures. FASEB J 14(6):A1114, 2000.

37. Hinton, D. M., Myers, Michael J., Raybourne R., Sotomayor, R. E., Shaddock, J., Warbritton, A., and Chou, M. Dynamics of the immune system of the rat in an intermittent dosing study with aflatoxin B1 (AFB_1). The Toxicologist 54:199-200, 2000.

38. Myers, Michael J. Validation of a PCR-based method for the detection of bovine-derived materials in complete animal feed. 2000 Midwest AOAC International Meeting.

39. English, L. L., Ayers, S. L., Zhao, S., Friedman, S. L., White, D. G., Wagner, D. D., McDermott, S. D., and Myers, Michael J. Presence of salmonella in pig ear dog treats obtained from retail stores. 2000 AAVLD Annual meeting.

40. Hinton, D. M., Myers, Michael J., Perloni, A., Hines, F., Raybourne, R., Sotomayor, R. E., Shaddock, J., Warbritton, A., Chou M, and Pestka, J. J. 2001. Enhanced histopathology with morphometry, immuno- and in situ staining in immunotoxicity studies of the mycotoxins, aflatoxin B1 (AFB1) and deoxnivalenol (DON). The Toxicologist, 2001.

41. Myers, Michael J., Farrell, D. E., Post, L. O. Inflammatory mediator production in swine following endotoxin-challenge with or without co-administration of dexamethasone. Scand J Immunology 54:S1; 3.23/667, 2001.

42. Myers, Michael J., Baarsch, M. J., and Murtaugh, M. P. Effects of pentoxifylline on inflammatory cytokine expression and acute pleuropneumonia in swine. Scand J Immunology 54:S1; 4.17/782, 2001.

43. LeClerc, J. E., Davis, P. A., Raybourne, R. B., Myers, Michael J., Payne, W. L., Barrett, K. L., and Cebula, T. A. Murine infection by natural mutators of *Salmonella enteritidis*: roles in overcoming host resistance and antibiotic therapy. 102nd General Meeting; American Society of Microbiology. Abstract A65, p13, 2002.

44. Scott, M. L., Farrell, D. E., and Myers, Michael J. Measurement of bovine inflammatory cytokines by RT-PCR using an ex vivo whole blood assay: relevance to endotoxin levels in animal pharmaceuticals. Joint American Dairy Scientists Association-American Society of Animal Scientists Meeting. J Anim Sci 80 (suppl 1):248, 2002.

45. Kawalek, J. C., Howard, K. D., Farrell, D. E., Derr, J. A., Cope, C. V., Jackson, J. D., and Myers, Michael J. Effect of low doses of pentobarbital (PtB) in beagles. 2002 ISSX annual meeting. Drug Metabolism Reviews 34 (suppl 1):122, 2002.

46. Kawalek, J. C., Farrell, D. E, Howard, K. D., Niwatananun, K., Weiner, M., and Myers, Michael J. Induction of hepatic drug metabolizing enzymes in swine: effects of classic inducers on CYPIA1. 2002 ISSX annual meeting. Drug Metabolism Reviews 34 (suppl 1):122, 2002.

47. LeClerc, J. E., Sahu, S. C,. Davis, P. A., Barrett, K. L., Raybourne, R. B., Myers, Michael J., Payne, W. L., and Cebula, T. A. Invasion and intracellular replication of MMR-defective Salmonella enteritidis in mouse hepatocyte cell line TIB-73.103st General Meeting; American Society of Microbiology. Abstract B-014, p36, 2003.

48. Myers, Michael J., Farrell, D. E., Heller, D. N., Yancy, H. F. Development of a PCR-based approach to detect canine-derived materials in dog food. FDA Science Forum, 2003.

49. LeClerc, J. E. Sahu, S. C., Davis, P. A., Barrett, K. L., Raybourne, R. B., Myers, Michael J., Payne, W. L. and Cebula, T. A. Newly identified roles of bacterial mutators in infection and colonization of mouse hepatocytes. FDA Science Forum, 2003.

50. Ekelman, K., Burkholder, W., Derr, J., Heller, D., Lovell, R, Myers, Michael J., and Kawalek, J. C. 2003. Risk Assessment for Pentobarbital in dry dog food. Society for Risk Assessment Abstract W12.5, 2003.

51. Myers, Michael J., Yancy, H. F., Farrell, D. E., Washington, J. D., Deaver, C. M., and Frobish, R. A. Assessment of tests marketed for detection ruminant proteins in finished feed. FDA Science Forum, 2006.

52. Peters, S. M., Yancy, H., Bremer, E., Monroe, J., Stubbs, J., and Myers, Michael J. Identification and verification of inflammatory biomarkers in swine using gene microarray analyses. 109th General Meeting; American Society of Microbiology, 2009.

53. Geary, E. D., Peters, S., Jones, Y., Orzechowski, K., Bremer, E., Monroe, J., Paul, D., Myers, Michael J., & Yancy, H. Identification of MDR Biomarkers in Canines using Gene Microarray Analyses. 2009. CDRH Summer Intern Poster Presentations.

54. Branham, K., Francis, N., Myers, Michael J., & Yancy H.F. Development of PCR Assays to Enforce FDA's Feed Ban. 2009. CDRH Summer Intern Poster Presentations.

55. Myers, Michael J., Washington, J. D., Callahan, L., Mason, J. A., Deaver, C. M., Farrell, D. E., and Yancy, H. F. Development, Evaluation, and Peer-Verification of a Rapid Real-Time PCR Method for the Detection of Animal Material. 3rd International Feed Safety Conference, 2009.

56. Swaim, H. L., Myers, Michael J., and Zhu, M. *In vitro* Identification of Novel MicroRNA Biomarkers of Swine Inflammation. 19th International Plant and Animal Genome Meeting, January, 2011.

57. Peters, S. M., Deaver, C.M., Jones, Y.L., Yancy, H.F., Kenyon, E., Esparza, J., Chiesa, O.A., Stubbs III, J.T., Lancaster, V., & Michael J. Myers. Validation of a swine systemic model of inflammation and the impact of a non-steroidal anti-inflammatory drug on the expression of mrna biomarkers. 10th International Congress of Inflammation. Inflammation Research 60 Suppl 1 S278, 2011.

58. Haile F. Yancy, Yolanda L. Jones, and Michael J. Myers. Development of a multiplex real-time pcr method for the detection of animal material. FDA Foods Program Science and Research Conference 2011

59. Chiesa, O.A., Heller, D., Wallace, G., Karanian, J.W., Pritchard W.F., Smith, S., Lopez, M., Condon, R.G., Kijak, P., Michael J. Myers, Ward, J.L., & von Bredow, J. Inhalation anesthesia induced by isofluorane alters penicillin disposition in swine tissues. FDA Foods Program Science and Research Conference. 2011.

60. Peters, S. M., Deaver, C.M., Jones, Y.L., Yancy, H.F., Kenyon, E., Screven, R., Esparza, J., Chiesa, O.A., Stubbs III, J.T., Lancaster, V., & Michael J. Myers. Identification of mRNA biomarkers which demonstrate non-steroidal anti-inflammatory drug efficacy in a swine model of systemic inflammation. FDA Foods Program Science and Research Conference. 2011.

61. Qiu, J., Michael J. Myers, Yancy, H., Troutman, L., Sharkey, M., Martinez, M., Modric, S., Leotta, B., & Gagne, M. Translation of pharmacogenomic biomarkers for safety signals to identify distinct subpopulations: a combined pharmacokinetic/pharmacodynamic approach. 2012 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop.

62. Deaver, C. M., Peters, S. M., Swaim, H. L., Yancy, H., & Michael J. Myers. Development of an in vitro carrageenan model of inflammation in swine. 2nd Annual FDA Foods Program science and Research Conference, 2012.

63. Screven, R., Kenyon, E.A., Boxer, L., Bigley, E., Skasko, M., Michael J. Myers, Yancy, H., & Zhu, M. Defining markers of stemness in canine mesenchymal stem cell products from various tissue sources. 2nd Annual FDA Foods Program science and Research Conference, 2012.

64. Michael J. Myers, Li, H., Swaim, H.L., Qiu, J., Troutman, L., Sharkey, M., Martinez, M., Modric, S., Leotta, B., Gagne, M., Yancy, H. Influence of ABCB1 genotype in collies on loperamide pharmacokinetics and pharmacodynamics in a dose-escalation study. 2nd Annual FDA Foods Program science and Research Conference, 2012.

65. Peters, S., Jones, Y.L., Michael J. Myers, Perrella, F., & Haile Yancy, H. Development of a Multiplex qPCR assay for the detection of ruminant DNA in raw materials used for crude heparin quality monitoring. 2nd Annual FDA Foods Program science and Research Conference, 2012.

66. Swain, M. D., Orzechowski, K.L., Swaim, H. L., Jones, Y. L., Robl, M. G., Tinaza, C. A., Michael J. Myers, Jhingory M. V.,Buckely, L. E. Lancaster, V. A. Yancy, H. F. P-glycoprotein substrate induced neurotoxicity in knock-in/knock-out mice with inserted mutated canine ABCB1. 2nd Annual FDA Foods Program science and Research Conference, 2012.

67. Kenyon, E.A., Peters, S.M, Jones, Y.L., Deaver, C.M., Michael J. Myers, & Yancy, H.F. In vitro characterization of inflammatory biomarkers across species. 2nd Annual FDA Foods Program science and Research Conference, 2012.

68. Myers, Michael J. Deaver, C.M., Peters, S., M., Swaim, H. L., and Yancy H. Molecular characterization of an alternative model of inflammation. 2013. American Association of Immunologists annual meeting. P 123 Abstract # 63.26.

69. Deaver, C.M., Kenyon, E., Peters, S.M, Prescott, M., Swaim, H., Tanke, K., Yancy, H.F., & Myers, Michael J. 2013. Identifying biomarkers associated with pain in swine using an in vitro inflammation model. Front. Immunol. Conference Abstract: 15th International Congress of Immunology (ICI). doi: 10.3389/conf.fimmu.2013.02.00497.

70. Deaver, C.M., Kanelakis, K.C., Yan, D, Mitchell, C., & Myers, Michael J. Myers. 2013. Development of an in vitro method to assess digestibility of veterinary protein therapeutics. 3rd Annual FDA Foods Program Science and Research Conference, Aug. 2013.

71. Zhu, M., Ming, Y., Swain, M., Myers, Michael J., Deaver, C., Wu, X., Stephens, R., Yancy, H.F. 2013. Identifying brain toxicity biomarkers in mice expressing the mutant canine ABCB1 gene in response to P-glycoprotein substrate drugs using whole-genome gene expression microarray. 3rd Annual FDA Foods Program Science and Research Conference, Aug. 2013.

72. Screven, R., Kenyon, E., Myers, Michael J., Yancy, H.F., Skasko, M., Boxer, L., Bigley III, E.C., Zhu, M. 2013. Immunophenotype and PCR array gene expression profile of mesenchymal stem cells derived from canine adipose tissue and bone marrow. 3rd Annual FDA Foods Program science and Research Conference, Aug. 2013.

73. Millington, N., Blair, E., Groesbeck, G., Johnson, A., Deaver, C., Howard, K., Mekoli, M., & Myers, Michael J. 2014. Use of positive reinforcement conditioning (socialization) in pigs to allow for unrestrained sample collection to reduce stress response. 4th Annual FDA Foods Program science and Research Conference, July 2014.

74. Zhu, M., Swaim, H., Swain, M., Myers, Michael J., Deaver, C., Wu, X., Jones, J.L., Yancy, H. F. 2014. Identifying potential biomarkers of neurotoxicity to predict the safety of P-glycoprotein substrates in transgenic mice expressing the mutated canine ABCB1 gene. 4th Annual FDA Foods Program science and Research Conference, July 2014.

75. Myers, Michael J., Deaver, C., Jones, J.L., Yancy, H.F. 2014. Loperamide-induced immune and inflammatory responses in Collies with ABCB1-1Δ mutation associated with ivermectin sensitivity. 4th Annual FDA Foods Program Science and Research Conference, July 2014.

76. Chiesa, O.A., Groesbeck, C., Frobish, S., MacDonald, M., Kouneski, A., Boliek, P., Myers, Michael J. Ultrasound-Guided external jugular catheterization in swine. 4th Annual FDA Foods Program Science and Research Conference, July 2014.

77. Lewandowski, A., Myers, Michael J. 2015. NSAIDs inhibit NFkβ activation to prevent inflammation. American Association of Immunologists annual meeting. IRC4P.602. Poster 57.19.

78. Deaver C. M., M. Peters, S.M., Swaim, H.L., Yancy, H., Myers, Michael J. 2015. Identifying biomarkers from an in vitro carrageenan model of inflammation in swine. American Association of Immunologists annual meeting. INM8P359, Poster 195.03

79. Li F., Howard K, Myers, Michael J. Developing the method for the quantitation of fexofenadine enantiomers in Collie plasma. 5th Annual FDA Foods Program Science and Research Conference, August 2015.

Oral Presentations with published abstracts:

1. Myers, Michael J., Pullen, J. K, Dickens, C. S., Schook, L. B. Alteration of macrophage (MO) differentiation into accessory and effector cells from exposure to dimethylnitrosamine (DMN) in vivo. Proceedings of the 6th International Congress of Immunology. 6:692, 1986.

2. Myers, Michael J. and Schook, L .B. Mechanisms for DMN induced changes of macrophage differentiation: alteration in the response to the regulatory signals controlling myelopoiesis. The Toxicologist 7:10, 1987.

3. Myers, Michael J., Lockwood, J. F., and Schook, L. B. Alteration in PGE_2 production following *in vivo* exposure to dimethylnitrosamine (DMN). The Toxicologist 8:149, 1988.

4. Myers, Michael J., Pullen, J. K., Eustis-Turf, E. and Schook, L. B. Regulation of IL-1 and TNF-alpha gene expression during bone marrow derived macrophage (BMDM) differentiation. FASEB J. 2(4):1228, 1988.

5. Awney, H., Mostafa, M. H., Gelboin, H. V., and Myers, Michael J. Cytochrome P-450 mediated H_2O_2 production and its role in mutagenesis. Free Radical Biology and Medicine 9,suppl 1:162, 1990.

6. Myers, Michael J. Human, pig and minipig cytochrome P450: why men are not pigs are not minipigs. 2002 ISSX annual meeting. Drug Metabolism Reviews 34(suppl 1):42.

7. Myers, Michael J, Yancy H. F., Farrell, D. E., Washington, J. D., Deaver, C. M. Development and validation of PCR-based methods for the detection of animal proteins in animal feed. 2006 American Oil Seed Chemists annual meeting. May 1, 2006.

8. Myers, Michael J, Yancy H. F., Farrell, D. E., Washington, J. D., Deaver, C. M., Frobish, R.A. Evaluation of commercial test kits marketed for the detection of animal proteins in animal feed. 2006 American Oil Seed Chemists annual meeting. May 1, 2006.

Oral Presentations without published abstracts:

1. Myers, Michael J. Overview of Immunology and Immunologic Research at the Center for Veterinary Medicine. FDA Immunology Workshop, 1995.

2. Jurgen von Bredow J, Myers, M.J. Wagner D., Valdes, J., Loomis, L., Zamani, K. Agroterrorism - Agricultural Infrastructure Vulnerability" Combined Conference on Food and Agriculture Security. September 28 - 30, 1998.

3. Myers, Michael J. Validation of a PCR-based Method for Detection of Bovine Materials. International Workshop on Diagnostics for Transmissible Spongiform Encephalopathies. September 20-22, 2000.

4. Myers M. J. Development of novel methods for detection of prohibited materials in animal feed and feed ingredients. Association of Southern Feed, Fertilizer and Pesticide Control Officials Annual Meeting, Ashville, NC, June 18th, 2002.

5. Myers, M. J. TSE research at FDA: Detection of prohibited materials in animal feed and feed ingredients. Albany, CA, USDA/ARS Workshop on TSE Research, July 11th, 2002.

6. Myers M. J. Novel approaches and probes for PCR detection of animal-derived materials. Annual AAFCO Meeting, Tucson, AZ, Jan 17th, 2003.

7. Myers, M. J. Immunochemical detection of prohibited animal proteins. Jan 17th, 2003, Annual AAFCO Meeting, Tucson, AZ.

8. Myers, M. J. 2004. Detection of prohibited animal proteins: tools in preventing the spread of BSE. BIO 2004, June 7th 2004, San Francisco, CA.

9. Myers, M. J. 2004. Development of PCR-based assays to detect animal-derived materials in animal feed. 12th Annual Nucleic Acid-Based Technologies Meeting, McLean, VA, June 22nd, 2004

10. Myers, M. J. Analytical methods to detect animal-derived materials in animal feed. Bothell, WA, FDA/ORAU Training Course VM3009A "Molecular and microscopic analysis of feeds for processed animal proteins. Aug 17th-20th, 2004

11. Myers, M. J. PCR-based analysis for animal proteins in animal feed. Bothell, WA, FDA/ORAU Training Course VM3009A "Molecular and microscopic analysis of feeds for processed animal proteins. Aug 17th-20th, 2004.

12. Myers, M. J. Case Studies. Bothell, WA, FDA/ORAU Training Course VM3009A "Molecular and microscopic analysis of feeds for processed animal proteins. Aug 17th-20th, 2004

13. Myers, M. J. Overview of analytical methods to detect processed animal proteins in animal feeds. "Prohibited materials in feed: analytical conference & workshop." Sacramento, CA, Dec 6th-11th, 2004

14. Myers, M. J. Assessment of analytical methods. "Prohibited materials in feed: analytical conference & workshop." Sacramento, CA, Dec 6th-11th, 2004.

15. Myers, M. J. University of Maryland, Department of Animal and Avian Sciences, Detection of BSE and animal proteins in animal feed, May 11, 2005.

16. Myers, M. J. Analytical methods to detect processed animal proteins: past, present and future. 2005 Annual Meeting, Association of Southern Feed, Fertilizer, and Pest Control Officials, June 21, 2005.

17. Myers, M. J. Overview of analytical methods for detection of animal proteins in feed and feed ingredients. 2010, 68th Meeting, Association of Southern Feed, Fertilizer, and Pest Control Officials, June 21, 2010.

18. Myers, M. J. Development, evaluation & validation of a real-time PCR method for detection of ruminant proteins in feed and feed ingredients. 2010, 68th Meeting, Association of Southern Feed, Fertilizer, and Pest Control Officials , June 23, 2010

GLP INFORMATION

JOB DESCRIPTION:

Study the bi-directional interactions of drugs used in veterinary medicine and the immune system, with special emphasis on the impact to food-producing animals. Special emphasis has been given for studies focused on understanding the correlation between changes in various markers of immunity such as antibody production, cell-mediated immunity, and cytokine production with the systemic metabolic and toxicologic changes that occur during bacteremia and septicemia. This research provides information on both adverse effects of drugs on immune homeostasis, as well as the impact of infectious disease on drug pharmacokinetics. An extension of this work centers on collaborative studies to identify and characterize cytochrome P450 enzymes in domestic food-producing animals such as swine and poultry, using enzymology and Western Blot analyses.

The second area of research centers on the development, modification and improvement of methods designed to detect protein-based, animal derived feed supplements using immunochemical and molecular biological techniques such as the polymerase chain reaction. An extension of this effort focuses on the validation of these same methods such that they can be readily transferred to FDA field laboratories as well as State laboratories. Another aspect of this work is our in-house evaluation of commercial test kits designed to detect various animal proteins in feed and feed ingredients, focusing on the performance of these tests against a objective acceptance criteria.

SPECIAL QUALIFICATIONS

1. Trained in tissue culture techniques and testing, including sterile techniques with over 26 years of laboratory experience.
2. Trained in radioactive safety techniques with over 30 years of laboratory experience.
3. Trained in various molecular techniques such as Northern Blotting, Southern Blotting, PCR, and Western Blotting as well a PAGE and agarose electrophoresis with over 28 years of laboratory experience.
4. Trained in the use of computer programs such as Excel, Word Perfect, Lotus Symphony, SigmaPlot, SigmaStat, PowerPoint, and MS Word with over 28 years experience.
5. Trained in the use of laboratory animal husbandry, handling, and sample collection with over 30 years of experience.
6. Trained in the use of large animal husbandry, handling, and sample collection with over 22 years of experience
7. Conduct clinical laboratory tests for albumin, GOT, GTP, bilirubin, neopterin, glucose, total protein and C3b in plasma, serum using diagnostic kits available from Sigma, ICN, or Quidel.
8. Trained in techniques to measure plasma, serum, and tissue culture fluid levels of IL-1, IL-2, IL-6, IL-10, TNF-alpha, using bioassay techniques in factor-dependent cell lines as well as ELISA kits from various vendors for IL-1β, IL-2, IL-6, TGF-B1, TNF-alpha, IL-8, IL-10, PGE_2, TXB_2, and neopterin.

9. Trained in immunochemical methodologies, including antisera generation & characterization, production & characterization of monoclonal antibodies, use and development of enzyme-linked immunosorbant assays (ELISA) & immunoaffinity chromatography, with over 26 years experience.

Additional Training:

1.	April 1989	NIH Authorized Radiation User Training (160 hours)
2.	Nov, 1990	Basic Food and Drug Law Course (4.5 days)
3.	Sept 25, 1991	Hazardous Waste Management (2.5 hours)
4.	Nov 19, 1991	Infectious Waste Management (1 hour)
5.	Dec 18, 1991	Driver Safety Training (1 hour)
6.	1990-present	On-the-job training in computer troubleshooting.
7.	January 1989	Basic Hazard Communication Training
8.	May 6/7, 1993	Leadership Workshop (16 hours)
9.	1991	FDA Bribery Awareness training and Computer Security training
10.	1990-2000	Annual Radiation Safety Update training (Feb 10, 2000 last)
11.	March 1999.	In house Good Laboratory Practices training
12.	Sept, 2000.	International Workshop on Diagnostics for Transmissible Spongiform Encephalopathies.
13.	June, 2000.	Workshop on implementation of 21 CFR Part 11 (3 Days).
14.	April, 2000	Electronic Records and Signatures Seminar (21 CFR Part 11) Workshop
15.	Oct, 2000	ISO 17025 training session
16.	Feb, 1989.	Chemical Safety in the Laboratory
17.	March, 1990	Standards of Ethical Conduct
19.	March, 1991	Hazardous Laboratory Chemicals & MSD's
20.	April, 1991	Bribery Awareness Training
21.	Sept 1991	Hazardous Waste Management
22.	Jan 1992	In House Good Laboratory Practices training
23.	1992	Basic Food and Drug Law Course (5 days)
24.	Feb, 1993	Guidelines for Conduct of Research in PHS
25.	1988	NIH training on animal handling, care, use and humane treatment
26.	Feb, 1993	OSB Animal Care and Use Training
27.	June, 1993	Introduction to Excel for Windows (2 days)
28.	Aug, 1991	Intermediate EXCEL for Windows (1 day)
29.	Sept, 1993	Review of the Office of Science-Beltsville Safety Manual and Update on Hazardous Materials Handling Procedures
30.	June, 1994	Advanced EXCEL for Windows (2 days).
31.	May, 1995	AIDS Awareness Workshop
32.	June, 1996	The Internet: A One Day Seminar (1 day)
34	Jan, 1995	PCR Techniques at Catholic Univ. (3 days)
35.	March 1997	Emerging Food borne Pathogens

36.	March, 1998	Safety Training
37.	Oct, 2000	Introduction to FDA Accreditation Initiative
38.	March, 2001	GLP Training (2 Hr)
39.	May, 2001	2 Hr. Safety Training (2 hr)
40.	May, 2001	IACUC Training (1 hr)
41.	May, 2001	21 CFR Part 11 Training (1 hr)
42.	Nov 27, 2001	IACUC 101 (ARENA) (8 hr).
43.	Dec 5 & 6, 2001	BSE/TSE Emerging Issues (1.5 days)
44.	Sept 2002	Annual Ethics Training
45.	April 2002	Good Laboratory Practices training (4 day course)
46.	March 5, 2003	Annual Radiation Safety Update Training
47.	September 28, 2003	IACUC Advanced Training Workshop
48.	Nov12-13, 2003	Immunogenicity of Recombinant Biological Therapeutics - A Practical Approach training workshop
49.	Nov 2004	Annual Ethics and Computer Security Training
50.	Nov 2005	Annual Ethics and Computer Security Training
51.	Nov 2006	Annual Ethics and Computer Security Training
52.	Dec 4, 2006	GLP Training (8 hr)
53.	Dec 5, 2006	IACUC/Animal Welfare training session (3 hr; taught course)
54.	Nov, 2007	Annual Ethics and Computer Security Training
55.	Feb 28, 2008	ITAS training
56.	June 16-20, 2008	Basic Project Officer Course
57.	June 24, 2008	Working with Difficult People
58.	Nov, 2008	Annual Ethics and Computer Security Training
59.	May 22-29, 2009	FDA Mentoring Skills/Leadership Development Program
60.	Nov, 2009	Annual Ethics and Computer Security Training
61.	April 13, 2010	Food Safety from the Perspective of the European Food Safety Authority
62.	May 25-27, 2010	GLP Training update/refresher.
63.	Nov, 2010	Annual Ethics and Computer Security Training
64.	June 23-25, 2010	The Writing System plain language writing course
65.	Feb 15-17, 2011	Phoenix/WinNonLin pharmacokinetic software training.
66.	May 25, 2011	AED/CPR training (3 hr)
67.	June 16, 2011	Meeting the Information Requirements of the Animal Welfare Act: A Workshop.
68.	Sept 2011 - present	Annual GLP Training update/refresher.
69.	Nov 2011- Present	Annual Ethics and Computer Security Training
70.	Aug 12, 2014	Relationship with Stakeholders
71.	Aug 13, 2014	Dangerous Documents
72.	Nov 4-6, 2014	Risk Management Training
73.	Nov 17-21, 2014	Contract Officers Representative (COR) Training

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Department of Health and Human Services
ATTN: Helio Chaves, Acting Executive Officer
Food and Drug Administration
Harvey W. Wiley Bldg., HFS-657
5100 Paint Branch Parkway
College Park, MD 20740

Date
April 5, 2017

License Number(s)
19-30771-01

Mail Control Number(s)
594437

Licensing and/or Technical Reviewer or Branch
Commercial, Industrial, R&D, & Academic Branch (Branch 2)

This is to acknowledge receipt of your: ☑ **Letter and/or** ☐ **Application** **Dated:** 03/29/2017

The initial processing, which included an administrative review, has been performed.

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

Follow the instructions on the form for submission.

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239