



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Mail Stop HFS-657
5100 Paint Branch Parkway
College Park, MD 20740-3835

March 3, 2015

Dennis Lawyer, Health Physicist
U.S. Nuclear Regulatory Commission
Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

Br. 2

NRC License No. 19-30771-01
Docket No. 03036120

RE: NRC License Amendment Request

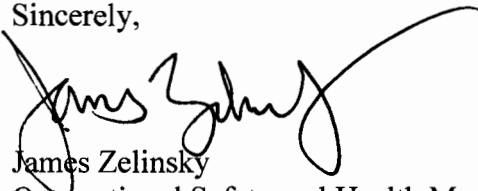
This correspondence is a request for a license amendment regarding the addition of an Authorized User at the U.S. Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN).

FDA CFSAN is requesting the addition of Pak Chu, Ph.D. as an Authorized User (AU) under our License No. 19-30771-01. A current copy of Dr. Chu's *curriculum vitae* is enclosed.

Dr. Chu has extensive experience in handling radioactive materials, specifically tritium and 14-carbon, and he has served as an AU under this license in the past. He has completed the forty-hour Authorized User's training at the National Institutes of Health as well as numerous radiation safety training courses while at the FDA.

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

586237
NMSS/RGNI MATERIALS-002

REC'D 1006 17 PM 104

PAK SIN CHU

[REDACTED]
(301)210-4583 (WORK)
[REDACTED]

PAK.CHU@FDA.HHS.GOV (EMAIL)

EDUCATION:

University of California, Davis

Degree: Ph.D.
Major: Agricultural & Environmental Chemistry
Date of Degree: [REDACTED]
Dissertation Title: The Pyrrolizidine Alkaloids: Relationship of Structural and Chemical Features to Their Metabolism

University of California, Davis

Degree: M.S.
Major: Physical Chemistry
Date of Degree: [REDACTED]
Thesis Title: Gas-phase NMR Studies of Six-Membered Ring Conformational Interconversion

University of California, Davis

Degree: B.S.
Major: Chemistry
Date of Degree: [REDACTED]

EXPERIENCE:

Team Leader (December, 2011- present); Chemist (December, 1992- 2011), OR, CVM, Food and Drug Administration, Laurel, MD.

This position serves as an expert in the areas of metabolism and biotransformation of animal drugs. The duties include, but are not limited to the following: review analytical methods submitted to FDA by the industry and by other government agencies; serve as the project officer on extramural research contracts for metabolism studies conducted for the Office of Research; conduct studies to isolate and identify drug metabolites in biological matrices; develop and validate methods for the determination of drug residues in food of animal origin. Additional duties include: conducting literature search, preparing study protocol, deciding on experimental approach, and preparing study reports.

Postdoctoral Scientist, Environmental Safety & Mass Spectrometry Dept./Drug Metabolism Dept., SmithKline Beecham Animal Health, West Chester, PA. September, 1991 - December, 1992

Duties included: identification of marker metabolite in milk with the aid of radiolabelled drugs; development and validation of analytical methods for determination of drug residues

in biological matrices, such as liver, kidney, muscle, fat, and milk. With the marker metabolite identified and the analytical method developed, the relationship between the marker and the total residues was determined. The developed method was then evaluated for potential interference by other commercially available drugs and for the stability of the marker metabolite in each matrix. All these studies were conducted under the GLP guideline. Additional duties included: supervising and providing guidance for subordinates, taking all necessary actions to ensure that the projects were completed on time while maintaining the highest quality of work, assisting supervisor (department manager) in solving problems in method development and in estimating project timing and resources. Other assignments included: preparing study protocol, writing up standard operating procedures (SOPs) and final report, presenting progress report in project review meetings, conducting internal audit on other staff member=s reports, and submitting research findings for publication.

Postgraduate Researcher/Research Assistant, Veterinary Pharm. & Tox. Dept., UC Davis, CA.
[REDACTED]

Research focused on the metabolism of pyrrolizidine alkaloids, which are phytotoxins that have caused numerous livestock losses and human poisonings. Radiolabelled pyrrolizidine alkaloids and their metabolites were isolated, characterized, and quantitated using appropriate techniques, such as high pressure liquid chromatography (HPLC), gas chromatography (GC) and gas chromatography-mass spectrometry (GC-MS). Additionally, I investigated the effects of inhibitors/inducers, routes of administration, and species difference on the biotransformation of pyrrolizidine alkaloids. H. J. Segall, Department of Pharmacology and Toxicology, School of Veterinary Medicine.

Graduate Student Assistant, Air Resource Board, State of California, Sacramento, CA. February,
[REDACTED]

Responsible for: analyzing ambient air samples for environmental toxicants (chlorinated and aromatic compounds) using gas chromatography (GC) with photoionization (PID) and electron capture (EC) detection, exploring new methods for sampling ambient air samples, conducting studies on the stability of air pollutants in Tedlar bags and in stainless steel canisters, and compiling analysis data.

Research Assistant, Environmental Toxicology Dept., UC Davis, CA. [REDACTED]
[REDACTED]

Research work involved residue analysis, method development, trace analysis of toxicants, in particular pesticides and their degradation products in vegetable. T. E. Archer, Department of Environmental Toxicology.

Research Assistant, Chemistry Department, UC Davis, CA.
[REDACTED]

Research involved the use of high resolution NMR spectroscopy to study conformational processes, such as nitrogen and ring inversion in the gas phase. Using computer simulated NMR spectra, I investigated the intramolecular vibrational relaxation and energy transfer

processes in six-membered ring compounds. Furthermore, the effects of polarity and isotopic substitution on conformational inversion were studied. N. S. True, Department of Chemistry.

Teaching Assistant, Chemistry Department, UC Davis, CA.

The primary responsibilities were to teach undergraduate laboratory courses, such as General Chemistry and Quantitative Analysis, and to assist teaching advance courses in Physical Chemistry and in Spectroscopy.

ADDITIONAL TRAINING:

2014- MidAmerica Toxicology Course	FDA/CVM
2014- Supervisor Skill Workshop	FDA/CVM
2014- FDA Computer Security Awareness Course	FDA/CVM
2014- Travel Training for Traveler and Preparers	FDA/CVM
2014- HHS 2014 Annual Ethics Training	FDA/CVM
2014- GLP Training	FDA/CVM
2014- Safety Awareness Training	FDA/CVM
2014- Introduction to Project Management	FDA/CVM
2014- Records Management	FDA/CVM
2013- FDA Computer Security Awareness Course	FDA/CVM
2013- HHS 2013 Annual Ethics Training	FDA/CVM
2013- GLP Training	FDA/CVM
2013- Safety Training	FDA/CVM
2013- SIEVE Training	Thermo Corp.
2013- FDACVM: FSMA Imports Team (FOT) - protecting the global food supply	FDA/CVM
2013- FDACVM: Regulatory Veterinary Drug Law	FDA/CVM
2013- Health and Human Services Travel Charge Card Training	FDA/CVM
2012- Q-Exactive Operator Training	Thermo Corp.
2012- HPO Refresh for Experienced CVM Employees	FDA/CVM
2012- How Are Animal Drugs, Food Additives and Feed Ingredients Reviewed at FDA to Ensure Food Safety	FDA/CVM
2012- Data Integrity Assurance & Investigations of Electronic Data and Computerized Systems	FDA/CVM
2012- FDA Import Operation with Focus on CVM-regulated Products	FDA/CVM
2012- Dangerous Documents: Avoiding Land Mines in Your Records and Emails	FDA/CVM
2012- Regulatory System for the Authorization of Veterinary Medicines in the European Union	FDA/CVM
2012- Annual Ethics Training	FDA/CVM
2012- Annual Radiation Safety Refresher Training	FDA/CVM
2012- FDA Computer Security Awareness Course	FDA/CVM

2011- Annual Ethics Training	FDA/CVM
2011- Annual Radiation Safety Refresher Training	FDA/CVM
2011- FDA Computer Security Awareness Course	FDA/CVM
2011- Annual Ethics Training	FDA/CVM
2011- GLP refresher course	FDA/CVM
2011- Introduction to R	FDA/CVM
2011- Requirements of the Animal Welfare Act: A Workshop	FDA/CVM
2011- Crucial Conversation	FDA/CVM
2011- Crucial Confrontation	FDA/CVM
2011- Technical Writing	FDA/CVM
2011- Advanced COTR Workshop	FDA/CVM
2011- HHS Appropriations Law	FDA/CVM
2010- FDA Computer Security Awareness Course	FDA/CVM
2010 - HHS Records Management for All Employees	FDA/CVM
2010- Annual Ethics Training	FDA/CVM
2010- Annual Waste Management Refresher Training	FDA/CVM
2010- Annual Radiation Safety Refresher Training	FDA/CVM
2010- Sciex AB 5500 LC-MS Operator Training	AB Sciex
2010- Good Laboratory Practices in the Real Word Part 11 and Electronic Records	FDA/CVM
2009- Annual Waste Management Refresher Training	FDA/CVM
2009- COTR Training program	GWU
2009- FDA Information Security Awareness Course	FDA/CVM
2009- Annual Waste Management Refresher Training	FDA/CVM
2009- Annual Radiation Safety Refresher Training	FDA/CVM
2009- Annual Ethics Training	FDA/CVM
2008- FDA Information Security Awareness Course	FDA/CVM
2008- Annual Waste Management Refresher Training	FDA/CVM
2008- Annual Radiation Safety Refresher Training	FDA/CVM
2008- Annual Ethics Training	FDA/CVM
2007- FDA Information Security Awareness Course	FDA/CVM
2007- Annual Waste Management Refresher Training	FDA/CVM
2007- Annual Radiation Safety Refresher Training	FDA/CVM
2007- Annual Ethics Training	FDA/CVM
2007- Animal Use Training	FDA/CVM
2007- Veterinary and Comparative Pharmacokinetic Workshop	FDA/CVM
2007- IACUC 101/201 PLUS	BioReliance
2006- Center for Veterinary Medicine - GLP Training	FDA/CVM
2006- FDA Information Security Awareness Course	FDA/CVM
2006- Annual Waste Management Refresher Training	FDA/CVM
2006- Annual Radiation Safety Refresher Training	FDA/CVM
2005- FDA Information Security Awareness Course	FDA/CVM
2005- Annual Waste Management Refresher Training	FDA/CVM
2005- Annual Radiation Safety Refresher Training	FDA/CVM

2005- GLP Regulations, Their History and Requirements	FDA/CVM
2004- Annual Waste Management Refresher Training	FDA/CVM
2004- Annual Radiation Safety Refresher Training	FDA/CVM
2004- FDA Information Security Awareness Course	FDA
2004- Quattro Micro Operations	Waters Corp.
2003- FDA Information Security Awareness Course	FDA
2003- Activity Time Reporting System	FDA/CVM
2003- Practical Grammar for Technical Writing	FDA/CVM
2003- Equipment Qualification Workshop	NCARAQA
2003- Annual Radiation Safety Refresher Training	FDA/CFSAN
2002- Introduction to Cyberlab User Training	FDA/CVM
2002- Waste Management and RCRA	FDA/CVM
2002- Project Management	FDA/CVM
2002- FDA Information Security Awareness Course	FDA
2002- Annual Radiation Safety Refresher Training	FDA/CFSAN
2001- TSQ 7000 LC-MS Operator Training	ThermoQuest
2001- Recruitment & Retention Seminar	FDA/CVM
2001- 21 CFR Part 11 Web Seminar	CDC Solutions
2001- Part 11 Overview	CDC Solutions
2001- Chemical Waste	FDA/CVM
2001- Cyberlab	Cyberlab
2001- GLP Training	FDA/CVM
2001- API 2000 LC-MS Operator Training	Applied Biosystems
2001- Navigating Electronic Records & Signatures Compliance Workshop	Agilent Technologies
2000- Annual Radiation Safety Refresher Training	FDA/CFSAN
2000- Workshop on Electronic Records, Electronic Signatures: Advanced Applications	PDA-TRI
1999- Annual Radiation Safety Refresher Training	FDA/CFSAN
1999- LCQ LC-MS Operators Training	ThermoQuest
1999- Animal Care & Use Seminar	FDA/CVM
1998- Annual Radiation Safety Refresher Training	FDA
1998- Building High-Performance Organizations for the Twenty-First Century	FDA/CVM
1997- Annual Radiation Safety Refresher Training	FDA
1997- Basic Radiation Safety Training	FDA/NCTR
1997- High Performance Organization	FDA/CVM
1997- Animal Medicinal Drug Use Clarification Act	FDA/CVM
1996- Annual Radiation Safety Refresher Training	FDA/CFSAN
1995- FDA FAME Communication Workshop	FDA/CVM
1995- Workshop on Supercritical Fluid Extraction/Chromatography	FDA/CFSAN
1995- Annual Radiation Safety Refresher Training	FDA/CFSAN
1994- Basic Project Officer Training	FDA/CVM
1994- Radiation Safety Training	FDA/CFSAN

1994- A Seminar on All-In-1 Version 3.0	FDA/CVM
1994- Workshop on ACurrently Implemented Industrial Applications of SFE@	EAS
1993- Workshop on "The Art and Science of Electrochemical Detection"	ESA, Inc.
1993- OSB Annual Training, Part II	FDA/CVM
1993- OSB Annual Training	FDA/CVM
1993- Workshop on Method Trials for Regulatory Analytical Methods	AHI
1993- Basic Food and Drug Law Course	FDA/CVM
1993- Annual Radiation Safety Refresher Training	FDA/CFSAN
1993- GLP Training	FDA/CVM
1992- Advanced GLP Training	SBAH
1992- Workshop on TurboChrom Software	SBAH
1992- Workshop on Animal Health Care	SBAH
1992- Course on HPLC System Model 1050 Maintenance	Hewlett Packard
1992- Workshop on Method Development	AHI
1991- Basic GLP Training	SBAH
1991- Radiation Safety Training	SBAH
1988- Operation Training on High Resolution NMR	UC Davis
1987- Operation Training on GC/MS and MS	UC Davis
1986- Radiation Safety Training	UC Davis
1982- Operation Training on High Resolution NMR	UC Davis

PUBLICATIONS

Kande Amarasinghe, **Pak-Sin Chu**, Eric Evans, Renate Reimschuessel, Nicholas Hasbrouck, and Hiranthi Jayasuriya "Development of a Fast Screening and Confirmatory Method by Liquid Chromatography–Quadrupole-Time-of-Flight Mass Spectrometry for Glucuronide-Conjugated Methyltestosterone Metabolite in Tilapia" *J. Agric. Food Chem.* (2012), 60, 5084–5088.

Pak-Sin Chu, Mayda I. Lopez, Ann Abraham, Kathleen R. El Said, Steven M. Plakas "Residue Depletion of Nitrofurans and Their Tissue-Bound Metabolites in the Channel Catfish (*Ictalurus punctatus*) after Oral Dosing" *J. Agric. Food Chem.* (2008) **56**: 8030-8034.

Mayda I. Lopez, Jeffery S. Pettis, Barton I. Smith, and **Pak-Sin Chu** "Multi-class Determination and confirmation of Antibiotic Residues in Honey Using LC-MS/MS." *J. Agric. Food Chem.* (2008) **56**, 1553-1559.

Badar B. Shaikh, Nathan Rummel, Charles Giesecker, **Pak-Sin Chu** and Renate Reimschuessel "Residue Depletion of Tritium-labeled Ivermectin in Rainbow Trout Following Oral Administration." *Aquaculture* (2007) **272**, 192-198.

Pak-Sin Chu and Mayda I. Lopez ADetermination of Nitrofurans Residues in Milk of Dairy

Cows Using Liquid Chromatography-Tandem Mass Spectrometry.@ *J. Agric. Food Chem.* (2007) 55, 2129-2135.

Mayda I. Lopez, Mark F. Feldlaufer, Anthony D. Williams, and **Pak-Sin Chu**
ADetermination and Confirmation of Nitrofurans Residues in Honey Using LC-MS/MS.@ *J. Agric. Food Chem.* (2007) 55, 1103-1108.

Pak-Sin Chu, Mayda Lopez, Stan Serfling, Charlie Gieseke, and Renate Reimschuessel
ADetermination of 17 α -Methyltestosterone in Muscle Tissues of Tilapia, Rainbow Trout, and Salmon Using Liquid Chromatography-Tandem Mass Spectrometry,@ *J. Agric. Food Chem.* (2006) 54, 3193-3198.

Pak-Sin Chu and Mayda I. Lopez ALiquid Chromatography-Tandem Mass Spectrometry for the Determination of Protein-Bound Residues in Shrimp Dosed with Nitrofurans.@ *J. Agric. Food Chem.* (2005), 53, pp. 8934-8939.

Pak-Sin Chu, Ro-Chen Wang, and Hiufung V. Chu ALiquid Chromatographic Determination of Fluoroquinolones in Egg Albumen and Egg Yolk of Laying Hens Using Fluorometric Detection.@, *J. Agric. Food Chem.* (2002) 50, 4452-4455.

Pak-Sin Chu, Dan J. Donoghue, and Badar B. Shaikh ADetermination of Total ^{14}C Residues of Sarafloxacin in Eggs of Laying Hens.@, *J. Agric. Food Chem.* (2000) 48, 6409-6411.

Badar Shaikh and **Pak-Sin Chu**, ADistribution of Total ^{14}C Residue in Egg Yolk, White and Tissues Following Oral ^{14}C Sulfamethazine Administration to Hens.@, *J. Agric. Food Chem.* (2000) 48, 6409-6411.

Badar Shaikh and **Pak-Sin Chu**, A Distribution of ^{14}C -Residue of Some Selected Poultry Drugs in Egg Albumen and Yolk@, *EuroResidue IV*, (2000) 1018-1023.

Patricia G. Schermerhorn, **Pak-Sin Chu**, and Maureen A. Ngoh, ADetermination of Cephalixin and Ceftiofur Residues in Bovine Milk by Liquid Chromatography with Ultraviolet Detection@, *J. AOAC Int.* (1998) 81, 973-977.

Mary C. Carson, Pak-Sin Chu, and Jurgen von Bredow, ATowards a Regulatory Method: Comparison and Validation of Multiresidue Procedure for Determination of β -lactam Antibiotics in Milk@, *Proceedings of Symposium on Veterinary Drug Residues in Food*, ACS Symposium Series (1996) 636, 108-120.

Patricia G. Schermerhorn, Pak-Sin Chu, and Philip James Kijak, ADetermination of Spectinomycin Residues in Bovine Milk Using Liquid Chromatography with Electrochemical Detection@, *J. Agric. Food Chem.* 1995, 43(8) 2122-2125.

Pak-Sin Chu, Richard Y. Wang, Thomas A. Brandt, and Chandralal A. Weerasinghe, ADetermination of Albendazole-2-aminosulfone in Bovine Milk Using High-Performance Liquid Chromatography with Fluorometric Detection@, *J. Chromatogr.* 1993, 620, 129-135.

Pak-Sin Chu, Mike Lamé, and H. J. Segall, A*In Vivo* Metabolism of Retrorsine and Retrorsine-N-oxide@, *Arch. Toxicol.* 1993, 67(1) 39-43.

Pak-Sin Chu and H. J. Segall, ASpecies Difference in the Metabolism of the Pyrrolizidine Alkaloid Retrorsine@, *Comp. Biochem. Physiol.* 1991, 100C(3), 683-686.

Pak-Sin Chu and Nancy S. True, APressure Dependent Gas-Phase ¹H NMR Studies of Tetrahydropyran Ring Inversion@, *J. Phys. Chem.* 1985, 89, 2625-2630.

Pak-Sin Chu and Nancy S. True, AGas Phase ¹⁹F NMR Studies of Ring Inversion in Cyclohexyl Fluoride@, *J. Phys. Chem.* 1985, 89, 5613-5616.

PRESENTATIONS

Chu, P.-S., "Overview of Rapid Animal Residue Detection Methodology" Oral presentation at the Workshop on Safety of Animal Drug Residues and Detections, Jinan, China, 2013

Chu, P.-S., "Animal Drug Residue Detection Methods and Multi-Drug Residue Methods Development" Oral presentation at the Workshop on Safety of Animal Drug Residues and Detections, Jinan, China, 2013

Chu, P.-S., "Development of Regulatory Methods for Measuring Drug Residues and Method Trials" Oral presentation at the IVDC and CVM Workshop on Veterinary Drug Safety Evaluation, Beijing, China, 2013

Chu, P.-S., "Animal Drug Residue Detection Methods and Multi-Drug Residue Methods Development" Oral presentation at the IVDC and CVM Workshop on Veterinary Drug Safety Evaluation, Beijing, China, 2013

Chu, P.-S., Johnson, T., Song, W., and Evans, E., "Determination of hormone residues in rainbow trout muscle using liquid chromatography-tandem mass spectrometry". Oral presentation at the 246th ACS National Meeting, Indianapolis, IN, (September 8-12, 2013).

Olumee-Shabon, Z., Nochetto, C., Rummel, N., and **P.-S. Chu**, "Method Validation and Quantitation of Zilpaterol in Bovine Liver and Muscle" Poster presentation at the 3rd Annual FDA Foods Program Science and Research Conference, White Oak, Maryland, 2013.

de Alwis, H., Nishshanka U., Jayasuriya, H., Chattopadhyaya, C., Ceric, O., **Chu, P.-S.**, Kijak, P., Reimschuessel, R., and Tkachenko, A., "Development of a Liquid Chromatography-Mass

Spectrometry Method for Toxic Phorbol Esters in Jerky Treat Products” Poster presentation at the 3rd Annual FDA Foods Program Science and Research Conference, White Oak, Maryland, 2013.

Chu, P.-S., Song, W., Johnson, T. L., Jayasuriya, H., Evans, E., Wei Song, Tricia Johnson, , and Eric Evans, “Liquid Chromatography-Tandem Mass Spectrometry for the Simultaneous Determination of Multiple Hormones in Fish Muscle” Oral presentation at the 49th Annual Florida Pesticide Residue Workshop, St. Pete Beach, Florida 2012

Chu, P.-S., “Human Food Safety of Veterinary Drugs” Oral presentation at the 2nd United States Food And Drug Administration (USFDA)-ASEAN Workshop On Food Safety For Aquaculture Products, Selangor, Malaysia, 2012

Chu, P.-S., “Overview of Laboratory Testing for Residues” Oral presentation at the 2nd United States Food And Drug Administration (USFDA)-ASEAN Workshop On Food Safety For Aquaculture Products, Selangor, Malaysia, 2012

Chu, P. S., “Detection of Drug Residues in Aquaculture Products” Oral presentation at the Aquaculture Food Safety Workshops, Multiple Cities in India, 2011.

Chu, P. S., “Laboratory Quality Management Systems: A Chemist’s Perspective” Oral presentation at the Aquaculture Food Safety Workshops, Multiple Cities in India, 2011.

Song, W., Johnson, T. L., Evans, E., and **Chu, P. S.** “Simultaneous Determination of Sixteen Hormones in Finfish Muscle Tissue by LC-MS/MS” Poster presentation at the 125th AOAC Annual Meeting and Exposition, New Orleans, LA, 2011.

Amarasinghe, K., Reimschuessel, R., Hasbrouck, N., Evans, E., Gieseke, C. **Chu, P. S.**, and Jayasuriya, H. “A Rapid Screening Method for the Detection of Methyltestosterone-17-O-Glucuronide in Tilapia” Poster presentation at the 125th AOAC Annual Meeting and Exposition, New Orleans, LA, 2011.

Jayasuriya, H. Reimschuessel, R., Hasbrouck N., Evans, E., Gieseke, C., Amarasinghe K. and **P. S. Chu** “Rapid Screening Method for the Detection of Methyltestosterone-17-O-Glucuronide in Tilapia. Poster presentation at the 1st Annual FDA Foods Program Science and Research Conference, White Oak, Maryland, 2011.

Song, W., Johnson, T. L., Eric Evans, E., and **Chu, P. S.**, “The Development of a Multiple-Residue Method for Detection of Hormones in Edible Fish Tissue by LC-MS/MS”, Poster presentation at the 1st Annual FDA Foods Program Science and Research Conference, White Oak, Maryland, 2011.

Chu, P. S., Johnson, T. L., Jayasuriya H., and Reimschuessel, R. “Development of Analytical Methods for the Determination of Steroid Hormones in Muscle of Tilapia Using Liquid Chromatography-Tandem Mass Spectrometry” Oral presentation at the 2010 International Chemical Congress of Pacific Basin Societies, Honolulu, Hawaii, 2010.

Johnson, T. L., **Chu, P. S.** “The Development of a Multi-Residue Method for the Determination of Steroid Hormones in Bovine Muscle Using LC-MS/MS” Poster presentation at the Florida Pesticide Residue Workshop, St. Pete’s Beach 2010.

Jayasuriya H., Reimschuessel, R., Hasbrouck, N., Evans, E. and **Chu, P. S.** “A Rapid Screening Method for the Detection of Methyltestosterone-17-O-glucuronide in Tilapia” Poster presentation

at the Sixth International Symposium on Hormone and Veterinary Drug Residue Analysis, Ghent, Belgium 2010.

Chu, P. S., Lopez, M. I., Abraham, A., El Said, K. R., Plakas, S. M. AAnalysis of nitrofurans residues in shrimp, channel catfish, and milk using liquid chromatography-tandem mass spectrometry@ Oral presentation at the 234th ACS National Meeting, Boston, MA, August 19-23, 2007.

Kijak, P. J., Heller, D. N., Li, H., Carson, M. C., **Chu, P. S.**, and Thomas, M. H. AAdvances in the Detection of Drug Residues in Animal Food Products at FDA.@ Oral presentation at the 38th Middle Atlantic Regional Meeting, Hershey, PA 2006.

Chu, P. S. and López, M.. ADetermination of Total Bound and Free Residues of Nitrofurans in Milk of Lactating Cows Using Liquid Chromatography/Tandem Mass Spectrometry.@ Poster presentation at the FDA Forum, Washington D. C. 2006.

López M., Feldlaufer, M. and **Chu, P. S.** ADetermination of Nitrofurans Residues in Honey.@ Poster presentation at the FDA Forum, Washington D. C. 2006.

Alderson, N., Babu, U., **Chu, P. S.**, Crone, T., Elkins, C., Fahmy, R., Gobburu, J., Johannessen, J., Kavanaugh, C., Kumar, S., Major, M., Manjanatha, M., Bright, R., Trinh, H., Torosian, S., Upoor, R., and Woods, T. ACommittee for the Advancement of FDA Science (CAFDAS): The FDA Scientist=s Liaison to the Commissioner=s Office@ Poster presentation at the FDA Forum, Washington D. C. 2006.

Chu, P. S. and Lopez, M. ATandem Mass Spectrometry for the Determination of Bound Residues of Nitrofurans in Channel Catfish.@ Poster presentation at the 11th Annual FDA Science Forum, Washington D.C. 2005.

Lopez, M. and **Chu, P. S.** ADetermination of 17 α -Methyltestosterone in Rainbow Trout.@ Poster presentation at the 11th Annual FDA Science Forum, Washington D.C. 2005.

Chu, P. S. AAssays for Nitrofurans in Shrimp: From Parent Drugs to Bound Metabolites.@ Oral Presentation at the Symposium on Analysis of Veterinary Drugs, Taiwan, 2004.

Chu, P. S. AUse of LC/MS/MS for the Determination of 17 α -Methyltestosterone in Tilapia.@ Oral Presentation at the Symposium on Analysis of Veterinary Drugs, Taiwan, 2004.

Lopez, M. and **Chu, P. S.** ADetermination of 17 α -Methyltestosterone in Tilapia.@ Poster presentation at the 10th Annual FDA Science Forum, Washington D.C. 2004.

Chu, P. S. and Lopez, M. ADetermination of Nitrofurans Residues in Shrimp.@ Oral presentation at the 40th Annual Florida Pesticide Residue Workshop, St. Pete=s Beach, July, 2004.

Chu, P. S. and Lopez, M. ADetermination of Nitrofurans Residues in Shrimp.@ Poster presentation at the 9th Annual FDA Forum on Regulatory Sciences, Washington D.C. 2003.

Heller, D. N. , Kijak, P. J., Carson, M. C., Reeves, V. B., O'Rangers, J., von Bredow, J., **Chu, P. S.**, Shaikh, B., Thomas M. H. A Proposal for Guidance from FDA Center for Veterinary Medicine on Confirmation by Mass Spectrometry. @ Oral presentation at the 114th AOAC International Annual Meeting, Philadelphia, PA, September 2000.

Shaikh, B. and **Chu, P. S.** A Distribution and Depletion of C-14 Residue of Some Selected Poultry Drugs in Egg Albumen and Yolk. @ Poster presentation at the EuroResidue IV Conference, Veldhoven, The Netherlands, May 8-10, 2000.

Chu, P. S., Donoghue, D. J. and Shaikh, B. A Determination of Total 14C-Residues of Sarafloxacin in Eggs of Laying Hens Distribution. @ Oral presentation at the 218th American Chemical Society National Meeting, New Orleans, LA, August 22-26, 1999.

Shaikh, B., **Chu, P. S.**, and G. D. Paulson A Distribution of Total 14C-Residue in Egg Yolk, White, and Tissues Following ¹⁴C-Sulfamethazine Administration to Hens. @ Oral presentation at the 218th American Chemical Society National Meeting, New Orleans, LA, August 22-26, 1999.

Chu, P. S., Ngoh, M.A., Schermerhorn, P.G. and von Bredow, J. A Multi-residue Determination of Beta-lactam Residues in Milk by HPLC. @ Poster presentation at the 1997 FDA Forum on Regulatory Sciences, Bethesda, MD, December 8-9, 1997.

Schermerhorn, P.G. Ngoh, M.A., **Chu, P. S.**, Kijak P. J. , Rummel, N. G. and H. F. Richter, J. A Procedure for the Determination of Cephapirin and Ceftiofur in Bovine Milk Using Liquid Chromatography with Ultraviolet Detection. @ Poster presentation at 111th AOAC International Meeting and Exposition, San Diego, CA, September 7-11, 1997.

Schermerhorn, P.G. Ngoh, M.A., **Chu, P. S.**, and H. F. Richter, J. A Procedure for the Determination of Cephapirin and Ceftiofur in Bovine Milk. @ Poster presentation at the 1996 FDA Forum on Regulatory Sciences, Washington D.C. December 5, 1996.

Carson, M. C., **Chu, P. S.**, and von Bredow, J. A Towards a Regulatory Method: Comparison and Validation of Multiresidue Procedure for Determination of β -lactam Antibiotics in Milk, @ Oral presentation at 209th American Chemical Society National Meeting, Anaheim, CA, 1995.

SKILLS

- ! Expertise in separation techniques, including LC-MS, HPLC, GC, TLC, paper, and column chromatography.
- ! Capable of operating the LCQ, API 2000, TSQ 7000, and Quattro Micro LC-MS systems as well as the Nicolet FT-200 MHz, FT-360 MHz and FT-500 MHz high resolution NMR spectrometers.
- ! Experienced with the handling of radioactive chemicals and the conduct of radiotracer studies.
- ! Familiar with gaseous sample preparation using high vacuum techniques.

- ! Able to read and write programs in Fortran.
- ! Proficient in software, such as TurboChrom, Analyst, Excalibur, MassLynx, TargetLynx, Excel, WordPerfect, Word, Quattro, and PowerPoint

This is to acknowledge the receipt of your letter application dated

03/03/2015, and to inform you that the initial processing which includes an administrative review has been performed.

19-30771-01 (amendment)
☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 586237
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader.