AstraZeneca

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June 24, 2010

James Dwyer, Chief
Nuclear Materials Safety Branch 2
United State Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: AstraZeneca Pharmaceuticals LP -- USNRC License No. 07-03990-01
Docket No. 030-03868

Dear Mr. Dwyer,

We respectfully request that the above-referenced license be amended as follows:

1. Radiation Safety Officer: Charles Elmore will replace Scott Petlick as Radiation Safety Officer (RSO) on License No. 07-03990-01. Dr. Elmore will assume the same duties and responsibilities historically performed by the facility's RSO. Exhibit 1 describes Dr. Elmore's qualifications to assume these responsibilities.

If you have any questions, please feel free to contact me at 302-886-3345 or Charles Elmore at 302-885-5934.

Thank you.

Sincerely,

Shaun Walsh
Vice President, Business Services

Enclosures

Cc: Charles Elmore
David Gobris
Barbara Ewing

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NMSS/RGN1 MATERIALS-002

AstraZeneca LP
1800 Concord Pike PO Box 15437 Wilmington DE 19850-5437

Tel 302 886 3000
www.astrazeneca-us.com

Exhibit 1

Radiation Safety Officer Applicant Experience and Training

Radiation Safety Officer Applicant: Charles S. Elmore

Experience	Dates	Location	Description
Principal Scientist	Jan 2004-present	AstraZeneca Pharmaceuticals, Wilmington, DE	Responsible investigator for radiosynthesis lab (2006-present). Responsible for radiation and chemical safety in two labs. Performed and supervised use of I-125, H-3, and C-14. Served on Radiation Safety Committee for AstraZeneca-Wilmington.
Research Fellow	Jun 1997 - Jan 2004	Merck Research Labs, Rahway, NJ	Performed and supervised radioactive syntheses with S-35 and C-14. Responsible for personal monitoring and follow-up wipe tests. Responsible for personal chemical and radiological safety for my team.

Radiation Specific Training	Dates and Duration	Location	Description
DOT & NRC Requirements for Shipping and Receiving Radioactive Materials	May 2010 4 hours	Radiation Safety Academy, Gaithersburg, MD	Shipping and Receiving Requirements for Class 7 materials.
Radiation Safety Officer	May 2010 40 Hours	Radiation Safety Academy, Gaithersburg, MD	Technical information and practical experience as a preparation to serve as an RSO.
Chem 496. Isotopically Labeled Compounds in Chemistry and Biology	Jan-May 1991 Semester long class	University of Illinois-Urbana, Champaign	Introduction to radioactivity including: 1. Characteristics, counting, safety, manipulation of radioactive substances. 2. Synthesis 3. Applications

Degree	Date Received	Major	Institution
Ph.D.	November 1997	Organic Chemistry	University of Illinois - Urbana, Champaign.
B.S.	May 1991	Chemistry	Rose-Hulman Institute of Technology

Professional Affiliations and Certifications

Radiation Safety Committee for AstraZeneca-Wilmington, 2006-present.
International Isotope Society, 1997-present.

See attachment for complete curriculum vitae.

CHARLES S. ELMORE

[redacted] [redacted] Home: [redacted]
Cell: [redacted]

PRINCIPAL CHEMIST

Worked for 13 years in the pharmaceutical industry for two large companies as a radiochemist. Led a motivated team of scientists in support of projects in all phases of drug discovery and development to include GMP-like preparations of samples for human clinical ADME and PET studies. Emphasized flexibility and team work to insure timely delivery of compounds to projects. Developed numerous novel methodologies to expedite syntheses which resulted in more than 20 publications and several invited lectures.

PROFESSIONAL EXPERIENCE

ASTRAZENECA PHARMACEUTICALS, Wilmington DE **2004-present**

Principal Scientist, Group Leader, Isotope Chemistry, CNS-Chemistry (2007-present)

Group leader responsible for radioactive (C-14 and H-3) and stable isotope labeling (SIL) of drug molecules in support of all Wilmington and some Montreal, Canada and Sodertalje, Sweden CNS projects.

- Managed two associates' work load, assigned priorities, designed syntheses, and outsourced compounds (when required) to support project needs and improved overall productivity of the group by 30% over 2 years.
- Co-authored SOP document for conducting of GMP-like syntheses of radiolabeled compounds for human ADME studies which has been used for all preparations company-wide since 2007.
- Selected compounds to target for PET investigation, developed labeling methodology and synthesized PET precursors in support of several projects which has allowed better translation of projects from animal to human and thus more accurate dosing in phase I studies.
- Served as responsible investigator (scientist responsible for laboratory's radioactive material, usage and safety and the corresponding paperwork) for two labs with no major radiochemical incidents.
- Used a combination of radiolabeling and LC/MS to accelerate the development of a mGluR2 selective radioligand which was recognized with an AstraZeneca Breakthrough award in 2008.

Scientist, Isotope Chemistry, CNS-Chemistry (2004-2007)

Team leader and individual contributor for the preparation of radioactive and stable isotope labeling of drug molecules in support of all Wilmington CNS projects.

- Organized the 2007 Excellence in Chemistry Symposium for over 200 attendees to include awardee and senior lecturer selection, advertising, and banquet organization for which feedback was uniformly positive and resulted in an AstraZeneca Extra Mile Award while finishing 20% under budget.
- Supported the development of a 5-HT_{1b} PET ligand which allowed the project to more rapidly advance the clinical candidate into humans.
- Prepared numerous C-14 labeled compounds for use in QWBA and ADME studies in support of IND filings.
- Prepared many tritium labeled compounds for use as radioligands and in receptor occupancy studies.

MERCK RESEARCH LABORATORIES., Rahway, NJ **1997-2004**

Research Fellow, Isotope Chemistry, Drug Metabolism (2003-2004)

Senior Research Chemist (1997-2003)

Team leader and individual contributor responsible for the preparation of C-14, S-35 and stable isotope labeled compounds in support of drug metabolism and basic research studies.

- Synthesized multiple compounds for human clinical ADME studies in support of NDA filings including the (now) marketed drugs etoricoxib (COX-2), aprepitant (NK1), and sitagliptin (DP IV).
- Developed methodology for conducting C-14 carbonylations which enabled much more rapid syntheses of complex drug molecules than was possible prior to the development of this methodology.

MERCK RESEARCH LABORATORIES *continued*

- Conducted a complex multi-step synthesis of a compound in two weeks, to address an adverse event that was observed in the clinic for a drug with a pending NDA which was recognized with a Special Achievement Award.
- Coordinated the C-14 synthesis of a drug candidate by a contract worker and was awarded an Award for Excellence for the ease with which the project was completed.

EDUCATION

Ph.D., Organic Chemistry, University of Illinois-Champaign, Urbana, Urbana, IL
Doctoral Dissertation: "Investigations into Terpene Biosynthesis through the use of Chiral Methyl Compounds" Advisor: Robert M. Coates
BS, Chemistry, Rose-Hulman Institute of Technology. Terre Haute, IN

PROFESSIONAL ACTIVITIES

Rose-Hulman Institute of Technology Chemistry Advisory Board, 2003 – 2007

American Chemical Society, member 1992 – Present
Co-chair of "Molecular Imaging in Drug Development and Chemistry II" session at the 236th ACS meeting (Aug 2008, Philadelphia, PA) sponsored by the Medicinal Chemistry Division.

International Isotope Society, member 1997 – Present
Co-chair for the "Applications of Isotopes in Pharmacology, Clinical and Medical Research" session at the 10th International Isotope Society meeting on 17 Jun 2009

TRAINING

Radiation Safety Officer with DOT certification – Radiation Safety Academy, 17-21 May 2010
cGMP for Pharmaceutical Production Supervisors – Center for Professional Advancement, 2-4 June 2010

Publications (* denotes corresponding author)

28. Charles S. Elmore * and Peter N. Dorff "Synthesis of Triphenylsilyl[$^{14}C_2$]acetylene for use in a Sonogashira Reaction", *Journal of Labelled Compounds and Radiopharmaceuticals*, 53, (**2010**), accepted for publication.

27. Charles S. Elmore* "Synthesis and Use of [^{14}C]Carbon Monoxide in Pd-Catalyzed Carbonylation Reactions" ", *Journal of Labelled Compounds and Radiopharmaceuticals*, 53, (**2010**), accepted for publication.

26. Charles S. Elmore, * Peter N. Dorff, J. Richard Heys "Syntheses of the Tricyclic Cores of Clozapine, Dibenzo[b,f][1,4]thiazepin-11(10H)-one, and Dibenzo[b,f][1,4]oxazepin-11(10H)-one in C-14 Labeled Form by [^{14}C]Carbonylation", *Journal of Labelled Compounds and Radiopharmaceuticals*, 53, (**2010**), accepted for publication.

25. John R. Zysk,* Dan Widzowski, Linda A. Sygowski, Katharine S. Knappenberger, Nathan Spear, Charles S. Elmore, Peter Dorff, Hongyan Liu, James Doherty and Vijay Chhajlani "Absence of direct effects on the dopamine D2 receptor by mGluR2/3-selective receptor agonists LY 354,740 and LY 379,268", *Synapse*, (**2010**), accepted for publication.

24. Teng Peng,* John Zysk, Peter Dorff, Charles Elmore, Peter Ström, Jonas Malmquist, Min Ding, David Tuke, Jennifer Werkheiser, Dan Widzowski, Laci Mrzljak, Donna Maier. "D2 Receptor Occupancy in Conscious Rat Brain is not Significantly Distinguished with [^{3}H]-MNPA, [^{3}H]-(+)-PHNO and [^{3}H]-raclopride",*Synapse*, (**2010**), 624-633.

23. Charles S. Elmore,* William E. Frietze, Donald W. Andisik, Glen E. Ernst, J. Richard Heys and Cathy Dantzman "Synthesis of a C-14 labeled Delta-Opioid receptor agonist by carbonylation", *Journal of Labelled Compounds and Radiopharmaceuticals*, 53, (**2010**), 394-397.

22. Charles S. Elmore* "The Use of Isotopically Labeled Compounds in Drug Discovery", *Annual Reports in Medicinal Chemistry*, 45, 515-534 (**2009**).

21. Donna L. Maier,* Cindy Sobotka-Briner, Min Ding, Mark Powell, Qiaoling Jiang, Geraldine Hill, J. Richard Heys, Charles S. Elmore, M Edward Pierson, and Ladislav Mrzljak "[*N* -methyl-$^3H_3$]AZ10419369 binding to the $5HT_{1B}$ receptor: in vitro characterization and in vivo receptor occupancy", *Journal of Pharmacology and Experimental Therapeutics*, 330, 342-351 (**2009**).

20. J. Richard Heys* and Charles S. Elmore "Meta-Substituent Effects on Organoiridium-Catalyzed *ortho*-Hydrogen Isotope Exchange", *Journal of Labelled Compounds and Radiopharmaceuticals*, 52, 189-200 (**2009**).

19. Jonathan Z. Ho*, Charles S. Elmore, Matthew P. Braun "Synthesis of a ^{14}C-labeled FPTase inhibitor *via* a Pd-catalyzed cyanation with $Zn(^{14}CN)_2$ and *via* bromo[^{14}C]acetic acid ", *Journal of Labelled Compounds and Radiopharmaceuticals*, 51, 399-403, (**2008**).

18. Charles S. Elmore*, Mark E. Powell, J. Richard Heys "Syntheses of AZ12320927 labeled with H-3, C-14, and H-2", *Journal of Labelled Compounds and Radiopharmaceuticals*, 51, 343-346, (**2008**).

17. Mark E. Powell*, Charles S. Elmore, Peter N. Dorff, J. Richard Heys "Investigation of Isotopic Echange Reactions using N-Heterocyclic Iridium (I) Complexes", *Journal of Labelled Compounds and Radiopharmaceuticals*, 50, 523-525 (**2007**).

16. Charles S. Elmore*, James E. Hall, Xiaomei Ye, and J. Richard Heys "Synthesis of two isotopically labeled $5HT_{1B}$ antagonists", *Journal of Labelled Compounds and Radiopharmaceuticals,* 50, 412-413 (**2007**).

15. Stella H.Vincent*, James R. Reed, Arthur J. Bergman, Charles Elmore, Bing Zhu, Shiyao Xu, David Ebel, Patrick Larson, Wei Zeng, Li Chen, Stacy Dilzer, Kenneth Lasseter, Keith Gottesdiener, John A. Wagner and Gary A. Herman "Metabolism and Excretion of the DPP-4 Inhibitor [^{14}C]Sitagliptin in Humans", *Drug Metabolism and Disposition,* 35 (4), 533-538 (**2007**).

14. Maria G. Beconi*, James R. Reed, Yohannes Teffera, Yuan-Qing Xia, Christopher J. Kochansky, David Q. Liu, Shiyao Xu, Charles Elmore, Suzanne Ciccotto, Donald F. Hora, Ralph A. Stearns, and Stella H. Vincent "Disposition of the Dipeptidyl Peptidase-4 Inhibitor Sitagliptin in Rats and Dogs", *Drug Metabolism and Disposition*, 35 (4), 525-532 (**2007**).

13. Cuyue Tang*, Raju Subramanian, Yuhsin Kuo, Sergey Krymgold, Ping Lu, Scott D. Kuduk, Christina Ng, Dong-Mei Feng, Chad Elmore, Eric Soli, Jonathan Ho, Mark G. Bock, Thomas A. Baillie, Thomayant Prueksaritanont "Bioactivation of 2,3-Diaminopyridine-Containing Bradykinin B_1 Receptor Antagonists: Irreversible Binding to Liver Microsomal Proteins and Formation of Glutathione Conjugates", *Chemical Research in Toxicology*, 18, 934-945 (**2005**).

12. Jonathan Z. Ho*, Charles S. Elmore, Michael A. Wallace, Dan Yao, Matthew P. Braun, Dennis C. Dean, David G. Melillo, Cheng-yi Chen. "Use of Di-*n*-butyl[^{14}C]formamide as a formylating reagent and synthesis of a C-14 labeled novel PDE-4 inhibitor", *Helvetica Chimica Acta* , 88 (5), 1040-1047 (**2005**).

11. Andy S. Zhang*, Charles S. Elmore, Marjorie A. Egan, David G. Melillo, Dennis C. Dean. "Use of Fluorous and Solid Phase Electrophiles as Scavengeres for Excess Amine in the Preparation of Sulfur-35 Labeled Radioligands", *Journal of Labelled Compounds and Radiopharmaceuticals*, 48 (2), 203–208 (**2005**).

10. Charles S. Elmore*, Dennis C. Dean, Yong Zhang, and David G. Mellilo "The Syntheses of [^{14}C] and [$^{13}C_2$,$^{15}N_3$]Aprepitant", *Journal of Labelled Compounds and Radiopharmaceuticals,* 47 (12), 837-846 (**2004**).

9. Allen N. Jones*, Matthew P. Braun, Dennis C. Dean, Charles S. Elmore, Yolanda Jakubowski, Herb Jenkins, David G. Melillo, Randy Miller, Steven Staskiewicz, Michael Wallace. "The Use of LC/MS to Indentify Unknown Radioactive Impurities in Clinical Tracers", *Synthesis and Applications of Isotopically Labelled Compounds, Proceedings of the 8th International Symposium of the International Isotope Society,* ed. D.C Dean, C.N. Filer and K.E. McCarthy, 289-292 (**2004**).

8. Andy Shiqiang Zhang*, Charles S. Elmore, Marjorie A. Egan, David G. Melillo, Dennis C. Dean. "Use of Fluorous Electrophiles as Scavengeres for Excess Amine in the Preparation of Sulfur-35 Labeled Radioligands" , *Synthesis and Applications of Isotopically Labelled Compounds, Proceedings of the 8th International Symposium of the International Isotope Society,* ed. D.C Dean, C.N. Filer and K.E. McCarthy, 333-336 (**2004**).

7. Charles S. Elmore*, Dennis C. Dean, Tina M. Marks, Matthew P. Braun, Marjorie A. Egan, David G. Melillo. "Synthesis of Two C-14 Labeled Cyclooxygenase-II Inhibitors *via* a Pummerer Degredation-Resynthesis Strategy", *Synthesis and Applications of Isotopically Labelled Compounds, Proceedings of the 8th International Symposium of the International Isotope Society,* ed. D.C Dean, C.N. Filer and K.E. McCarthy, 15-18 (**2004**).

6. Charles S. Elmore*, Dennis C. Dean, Robert J. DeVita, David G. Melillo "Synthesis of two non-peptidyl GnRH receptor antagonists via [^{14}C]carbonylation", *Journal of Labelled Compounds and Radiopharmaceuticals* 46 (10), 993-1000 (**2003**).

5. Charles S. Elmore*, Dennis C. Dean, Yong Zhang, Carter Gibson, Herb Jenkins, Allen N. Jones and David G. Melillo "Synthesis of [C^2H_3]Methotrexate and [C^2H_3]7-Hydroxymethotrexate", *Journal of Labelled Compounds and Radiopharmaceuticals 45*, 29-36 (**2002**).

4. Kelem Kassahun*, Paul G. Pearson, Wei Tang, Ian McIntosh, Kwan Leung, Charles Elmore, Dennis Dean, Regina Wang, George Doss and Thomas A. Baillie "Studies on the Metabolism of Troglitazone to Reactive Intermediates in Vitro and in Vivo. Evidence for Novel Biotransformation Pathways Involving Quinone Methide Formation and Thiazolidinedione Ring Scisson", *Chemical Research in Toxicology*, *14*, 62-70 (**2001**).

3. Charles S. Elmore*, Dennis C. Dean, Kun Liu, A. Brian Jones and David G. Melillo "The Synthesis of a C-14 Labeled Insulin Receptor Activator.", *Synthesis and Applications of Isotopically Labelled Compounds, Volume 7,* ed. U. Pleiss and R. Voges, 224-227 (**2001**).

2. Charles S. Elmore*, Dennis C. Dean, and David G. Melillo "A Convenient Method for [^{14}C]Carbonylation Reactions", *Journal of Labelled Compounds and Radiopharmaceuticals*, *43*, 1135-1144 (**2000**).

1. Robert M. Coates*, Charles S. Elmore, Rodney B. Croteau*, David C. Williams, Hiromi Morimoto, and Philip G. Williams. "Stereochemistry of the Methyl $\rightarrow$ Methylene Elimination in the Enzyme-Catalysed Cyclization of Geranyl Diphosphate to (4*S*)-Limonene", *Journal of the Chemical Society, Chemical Communications*, 2079-2080 (**1997**).

Published Meeting abstracts

2. J. Andersson*, M.E. Pierson, S.J. Finnema, B. Gulyas, N. Seneca, J.R. Heys, C. Elmore, L. Farde, C. Halldin " Development of a PET Radioligand for the 5-HT1B Receptor from a Compound Library: Radiosynthesis, Characterization, in the Primate Brain and Metabolite Analysis", *Journal of Labelled Compounds and Radiopharmaceuticals*, 52, S74 **(2009)**.

1. G. Åberg, F. I. Aigbirhio, E. Alexakis, N. Al-Maharik, M. Almi, Y. Ambacher, S. Andersson, A. Athlan, G. Badman, S. A. Baldwin, M. Baumann, I. R. Baxendale, N. P. Botting, R. A. Bragg, J. A. Brown, A. Burton, N. Bushby, K. Cable, G. Campbell, R. Carr, M. Carroll, L. Chen, M. Christlieb, P. Davies, G. J. Ellames, W. Ellis, C. Elmore, T. Fryatt, N. Geach, J. R. Harding, S. Hartmann, S. Harwood, J. J. Hayward, P. J. F . Henderson, R. B. Herbert, J. R. Heys, S. Hölzl, M. D. Hopkin, P. Horn, T. Ilyas, S. Irvine, S. D. Jackson, J. Jin, A. Keats, A. R. Kennedy, W. J. Kerr, M. O. Kitching, C. Landreau, S. Lanners, R. Lawrence, K. W. M. Lawrie, S. V. Ley, G. Little, W. J. S. Lockley, D. Maier, C. Manning, A. McNeill, D. A. Middleton, S. Montgomery, J. J. Morrison, L. Mrzljak, J. Newman, J. Newsome, N. Nikbin-Roudsari, G. N. Nilsson, M. F. Oldfield, S. G. Patching, D. J. Procter, G. Randall, A. A. Robertson, C. S. Rummel, D. Rustidge, R. Sherhod, N. Shipley, C. D. Smith, C. J. Smith, D. I. Smith, C. Song, L. Tamborini, I. Waterhouse, A. Watts, J. L. Werkheiser, G. Williams, C. L. Willis, P. Woodward, R. Yan, G. Young, Q. Zhang, Journal of Labelled Compounds and Radiopharmaceuticals, 51, 247-261 **(2008)**.

Oral Presentations (* denotes invited talk):

9. Charles S. Elmore, William E. Frietze, Donald W. Andisik, Glen E. Ernst, J. Richard Heys and Cathy Dantzman "Synthesis of a C-14 labeled Delta-Opioid receptor agonist by carbonylation" at the 10th International Isotope Society meeting on 18 Jun 09.

8. *Charles S. Elmore "The Use of Radioactivity in Drug Discovery", James Madison University, 20 Feb 2009.

7. *Charles S. Elmore, Mark E. Powell, Peter N. Dorff, J. Richard Heys, Jan Anderson, David A. Killick, John R. Harding, Amy M. Medd, Donna Maier, Cynthia Sobotka-Briner,Qiaoling Jiang, Geraldine Hill, Dandan Wang, Minli Zhang, Ladislav Mrzljak, Daniel C. Hill, Dennis J. McCarthy, Sjoerd J. Finnema, Katarina Varnäs, Akihiro Takano, Per Karlsson, Balázs Gulyás, Chi-Ming Lee, William Potts, Nicholas Seneca, Svante Nyberg, Lars Farde, Christer Halldin, and M. Edward Pierson "Synthesis of radiolabeled tracers in support of discovery efforts to develop a 5-HT_{1B} antagonist drug", International Isotope Society, 21st Central US Chapter Meeting, St. Louis, MO, 6 June 08.

6. Charles S. Elmore "The Use of Radioactivity in Drug Discovery", Illinois Wesleyan University, 18 April 2008.

5. Charles S. Elmore, Dennis C. Dean, Tina M. Marks, Matthew P. Braun, Marjorie A. Egan, David G. Melillo. "Synthesis of Two C-14 Labeled Cyclooxygenase-II Inhibitors *via* a Pummerer Degredation-Resynthesis Strategy", 8th International Isotope Society Symposium, Boston, MA, 5 Jun 2003.

4. Charles S. Elmore, Dennis Dean, Matthew Braun, Frank Tang, Yong Zhang, Gregory Gatto, Michael Wallace, and David Melillo "The syntheses of several labeled forms of aprepitant and another tachykinin neurokinin-1 antagonist", International Isotope Society: 20th Northeast U.S. Meeting, Somerset, NJ, 11 Oct 2002.

3. Charles S. Elmore "Use of Radioactivity in Drug Metabolism and Labeled Compound Synthesis", Merck and Co., Inc. Department of Health Physics, 21 May 2002.

2. *Charles S. Elmore "Radioactivity and the Pharmaceutical Industry: Organic Synthesis of Radiolabeled Drugs", Illinois Wesleyan University, 5 April 2002.

1. Charles S. Elmore, Dennis C. Dean, and David G. Melillo. "Convenient Generation of ^{14}CO for Carbonylation Reactions.", International Isotope Society: 16th Northeast U.S. Meeting, Princeton, NJ, 30 Oct 1999.

One internal oral presentation to the Discovery Organization at AstraZeneca.

Posters Presentations:

11. Charles S. Elmore, Dandan Wang, Minli Zhang "Synthesis and metabolism of a potent 5-HT_{1B} antagonist", 236th American Chemical Society National Meeting, Philadelphia, PA, 17 Aug 2008.

10. Charles Elmore, Jennifer L. Werkheiser, J. Richard Heys, Ladislav Mrzljak, Donna Maier "*In vivo* receptor occupancy of alpha 7 neuronal nicotinic receptor agonists in rat brain using a high affinity tritium-labeled radioligand", 16th International Isotope Society UK Group Meeting, Hinxton Hall, England, 1 Nov 2007.

9. Charles S. Elmore and J. Richard Heys "Selectivity between nonequivalent ortho sites of organoiridium-catalyzed deuterium exchange in meta-substituted substrates", 234th American Chemical Society National Meeting, Boston, MA, 21 Aug 2007. (also presented at the NE Regional Isotope Society meeting in Princeton, NJ, 25 Oct. 2007)

8. Charles S. Elmore James E. Hall, Xiaomei Ye, and J. Richard Heys "Synthesis of two isotopically labeled $5HT_{1B}$ antagonists", 8th International Isotope Society Symposium, Edinbough, Scotland, 15 Jul 2006.

7. Charles S. Elmore and J. Richard Heys "Synthesis of [^{3}H]M-549865", International Isotope Society: 22nd Northeast U.S. Meeting, Uncasville, CT, 21 Oct 2005.

6. Charles S. Elmore, Dennis C. Dean, Tina Marks, Matt Braun, Nathan Yu, Yong Zhang, Conrad Raab, Rominder Singh, Lixia Jin, David Melillo, Christopher J. Dinsmore, and Theresa M. Williams "The Synthesis and Metabolism of Two Isotopomers of a C-14 Labeled Farnesyl-Protein Transferase Inhibitor", 224th American Chemical Society National Meeting, Boston, MA, 19 Aug 2002.

5. Charles S. Elmore, Dennis C. Dean, Robert J. DeVita, and David G. Melillo "Synthesis of Two Non-Peptidyl GnRH Antagonists *via* C-14 Carbonylation.", International Isotope Society: 19th Northeast U.S. Meeting, Pearl River, NY, 25 Oct 2001.

4. Yong Zhang, Charles S. Elmore, Dennis C. Dean, Carter Gibson, Herb Jenkins, Allen N. Jones, and David G. Melillo "Synthesis of CD_3-Labeled Methotrexate and 7-Hydroxymethotrexate", International Isotope Society: 18th Northeast U.S. Meeting, King of Prussia, PA, 26 Oct 2000.

3. Charles S. Elmore, Dennis C. Dean, Kun Liu, A. Brian Jones, and David G. Melillo. "The Synthesis of a C-14 Labeled Insulin Receptor Activator.", 7th International Isotope Society Symposium, Dresden, Germany, 18 Jun 2000.

2. Charles S. Elmore, Dennis C. Dean, and David G. Melillo. "Synthesis of Dibutyl [^{14}C]formamide for Use as a Vilsmeier [^{14}C]Formylation Reagent.", International Isotope Society: 17th Northeast U.S. Meeting, Morristown, NJ, 21 Oct 1999.

1. Elmore, Charles S., Coates, Robert M.; Croteau, Rodney B.; Williams, David, C; Morimoto, Hiromi.; Williams; Philip G. "Investigation of the $CH_3 \rightarrow CH_2$ Elimination in the Biosynthesis of Limonene through the Use of (*R*)-9-Chiral Methyl Geranyl Diphosphate." International Isotope Society: 10th Central U.S. Meeting, Indianapolis, IN, 23 May 1997.

Two internal poster presentations at Merck (May 1999 on Vilsmeier chemistry and May 2000 on an unreported topic) and eight at AstraZeneca (7 Apr 2005, 7 Jun 2006, 14 Nov 2006, 27 Jun 2007, 15 Nov 2007, 12 Jun 08, 13 Nov 08, 11 Jun 09); six on otherwise undisclosed material and one similar to the 2007 ACS presentation and one similar to the 2009 IIS pres

This is to acknowledge the receipt of your letter/application dated

6/24/2010, and to inform you that the initial processing which includes an administrative review has been performed.

AMEND. 07-03990-01

[✓] 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.

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NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader