UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 6, 2008

Docket No. 030-31689 License No. 19-07538-05
Control No. 142344

John M. Strong
Acting Director
Department of Health and Human Services
U.S. Food and Drug Administration
Laboratory of Clinical Pharmacology
Office of Testing and Research
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Life Sciences Building #64, Room 2022
Silver Spring, MD 10993

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, LICENSE AMENDMENT, CONTROL NO. 142344

Dear Mr. Strong:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 9

cc:
Robert Parker, Ph.D., Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML081610741.wpd

SUNSI Review Complete: EUllrich
After declaring this document "An Official Agency Record" it **will** be released to the Public.

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NAME	EUllrich ***/EAU/***							
DATE	6/5/08							

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated April 24, 2008,
1. Laboratory of Clinical Pharmacology Office of Testing and Research Center of Drug Evaluation and Research	3. License No. 19-07538-05 is amended in its entirety to read as follows:
2. U. S. Food and Drug Administration, DHHS Life Sciences Building #64, Room 2022 10903 New Hampshire Avenue Silver Spring, MD 20993	4. Expiration Date: October 31, 2015 5. Docket No. 030-31689

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Hydrogen 3	A. Any	A. 90 millicuries
B. Carbon 14	B. Any	B. 80 millicuries
C. Sulfur 35	C. Any	C. 10 millicuries

9. Authorized use:

A. through C. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at the Life Sciences Building #64, 10903 New Hampshire Avenue, Silver Spring, Maryland.

11. Licensed material shall be used by, or under the supervision of Lawrence Anderson, Ph.D., Neil Hartman, Ph.D., Aspandiar S. Katki, Raymond W. Klecker, Robert Parker, Ph.D., Edward Radden, and John Strong, Ph.D.

12. The Radiation Safety Officer (RSO) for this license is Robert Parker, Ph.D.

13. Licensed material shall not be used in or on human beings.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License No.
19-07538-05

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030-31689

Amendment No.
09

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.

15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated June10, 2005 [ML051780367]
    B. Letter dated September 23, 2005 [ML052720133]

For the U. S. Nuclear Regulatory Commission

Original signed by Elizabeth Ullrich

Date June 6, 2008 By _____

Elizabeth Ullrich
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406