



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

October 24, 2006

Docket No. 03036825
Control No. 139328

License No. 06-30933-02

Howard Uderman, M.D.
Medical Director
Pfizer New Haven Clinical Research Unit
1 Howe Street
New Haven, CT 06510

SUBJECT: PFIZER NEW HAVEN CLINICAL RESEARCH UNIT, LICENSE AMENDMENT,
CONTROL NO. 139328

Dear Dr. Uderman:

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, Industrial, and Academic Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 1

H. Uderman
Pfizer New Haven Clinical Research Unit

2

cc:
Subhashis Banerjee, M.D., Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML062970073.wpd

SUNSI Review Complete: DLawyer

After declaring this document "An Official Agency Record" it will be released to the Public.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	DLawyer/DRL							
DATE	10/24/2006							

OFFICIAL RECORD COPY

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.

<p style="text-align: center;">Licensee</p> <p>1. Pfizer New Haven Clinical Research Unit</p> <p>2. 1 Howe Street New Haven, CT 06510</p>	<p>In accordance with the letter received August 25, 2006</p> <p>3. License number 06-30933-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date April 30, 2015</p> <hr/> <p>5. Docket No. 030-36825 Reference No.</p>
---	---

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 31.11</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 200 millicuries</p> <p>B. 10 millicuries</p>
<p>9. Authorized use:</p> <p>A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.</p> <p>B. <u>In vitro</u> studies.</p>		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at 1 Howe Street, New Haven, Connecticut.
- 11. The Radiation Safety Officer for this license is Subhashis Banerjee, M.D.
- 12. Licensed material is only authorized for use by, or under the supervision of:
 - A. Individuals permitted to work as an authorized user in accordance with 10 CFR 35.13 and 35.14.
 - B. The following individuals are authorized users for medical use as indicated:

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
06-30933-02

Docket or Reference Number
030-36825

Amendment No. 1

Authorized Users

Thomas E. Murtaugh, M.D.

Subhashis Banerjee, M.D.

Joyce Van Winkle, D.P.M.

Material and Use

35.100; *In vitro* studies

In vitro studies

In vitro studies

13. The licensee shall possess and use byproduct material for human research use in accordance with the prescriptive and performance criteria in all sections of 10 CFR Part 35.
14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. 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 January 7, 2005 (ML050380236)
- B. Letter dated April 15, 2005 (ML051230273)

For the U.S. Nuclear Regulatory Commission

Date October 24, 2006

By **Original signed by Dennis R. Lawyer**

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406