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

August 22, 2011

Docket No. 03036825 License No. 06-30933-02
Control No. 575659

Steven C. Boike, Pharm.D.
Chief Operating Officer
Pfizer Clinical Research Units
Pfizer Inc.
500 Arcola Road
Collegeville, PA 19426

SUBJECT: PFIZER NEW HAVEN CLINICAL RESEARCH UNIT, LICENSE AMENDMENT, CONTROL NO. 575659

Dear Dr. Boike:

This refers to the letter dated July 18, 2011 informing us of the resignation of Dr. Gabriella Bedarida and the letter dated August 10, 2011 requesting to temporarily place this license into an inactive status. Enclosed with this letter is the amended license limiting the authorized use of byproduct material to possession and storage.

Please note that the enclosed license is effective for two years from the date of this letter and does not authorize the use of byproduct material. In order to reinstate medical use under 10 CFR 35.100, the license will need to be amended to add a qualified authorized user and a new Radiation Safety Officer who meets the requirements of 10 CFR 35.50.

Although you requested to suspend the authorization to perform in vitro studies under 10 CFR 31.11, please note that it may be possible for you to carry out these studies under a general license. The process for registering to perform in vitro testing under a general license is described in 10 CFR 31.11(b)(1).

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 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Sandra Gabriel

Sandra Gabriel
Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 7

cc:
Joyce Van Winkle, D.P.M., Director of Operations, Pfizer New Haven Clinical Research Unit

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