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

March 21, 2005

Docket No. 03036825 License No. 06-30933-02
Control No. 136330

Walid Abi-Saab, Ph.D.
Medical Director
Pfizer New Haven Clinical Research Unit
1 Howe Street
New Haven, CT 06510

SUBJECT: PFIZER NEW HAVEN CLINICAL RESEARCH UNIT, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 136330

Dear Dr. Abi-Saab:

This is in reference to your application dated January 7, 2005 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. Under Item 7.C. on page 4 of the application, you state that the compounds received by your institution will be under approved Investigational New Drugs (INDs). Current NRC policy in writing licenses is to include the IND number, the institution that makes the licensed material, and the chemical form of the licensed material. Please submit the above information for review.

2. Your submission does not indicate what uses the named authorized users are to supervise. Please confirm that Irina V. Kaplan, Ph.D. and Joyce Van Winkle, Ph.D. are to supervise licensed activities under 10 CFR 31.11. If they are to supervise the use of licensed material under 10 CFR 35.100, then you need to submit their training and experience as required by 10 CFR 35.190 or 35.910.

3. Your submission appears to indicate that Thomas E. Murtaugh, M.D. is to be listed as an authorized user for activities under 10 CFR 35.100 and 31.11. In order to approve this authorization, please submit training and experience for Dr. Murtaugh as required by 10 CFR 35.190 or 35.910. Also, please provide a copy of Dr. Murtaugh's medical license allowing the practice of medicine in the State of Connecticut.

4. Please confirm that you have equipment to measure dosages of unsealed byproduct material. Also, if you have such equipment, state that, "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."

5. Please note that in Item 10.H. on page 8 of the application, you refer to the regulations in 10 CFR 35.69 for the safe use of unsealed licensed material. 10 CFR 35.60 refers to the labeling of syringes, syringe shields, vials, and vial shields, and therefore need not be cited in this section.

Current NRC regulations and guidance are available at the NRC Web sites listed below or 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).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 136330. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original signed by Steven Courtemanche

Steven Courtemanche
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Irina V. Kaplan, Ph.D., Radiation Safety Officer

NRC Web site addresses
NRC regulations
http://www.nrc.gov/reading-rm/doc-collections/cfr/
Licensing guidance
http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/
General Policy and Procedure for NRC Enforcement Actions
Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf
206 of the Energy Reorganization Act of 1974
http://www.nrc.gov/who-we-are/governing-laws.html

DOCUMENT NAME: E:\Filenet\ML050800046.wpd

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	SCourtemanche/src							
DATE	03/21/2005							

OFFICIAL RECORD COPY