

From: Dennis Lawyer
To: "Uderman, Howard D" <Howard.D.Uderman@pfizer.com>
Date: Thu, Oct 5, 2006 8:18 AM
Subject: RAI, Pfizer New Haven Clinical Research Unit

License No.:06-30933-02
Docket No: 03036825
Control No: 139328

Pfizer New Haven Clinical Research Unit, Request for Additional Information Concerning Application for a License Amendment, Control 139328

Dear Dr. Uderman,

This is in reference to your letter received August 25, 2006 requesting for amendment to Nuclear Regulatory Commission License No. 06-30933-02. We have also received your letter dated September 20, 2006. In order to continue our review, we need the following additional information:

1) In your letter of September 20, 2006, you did not list that Dr. Banerjee had obtained the experience requirements of 10 CFR 35.50(b)(ii). These include:

One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(C) Securing and controlling byproduct material;

(D) Using administrative controls to avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(F) Using emergency procedures to control byproduct material; and

(G) Disposing of byproduct material

2) Additionally 10 CFR 35.50(d) requires that he has obtained written attestation, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph 10 CFR 35.50(e) and in paragraphs 35.50(a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) or (c)(2) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your amendment.

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 139328. If you have technical questions regarding this letter, please call me at (610) 337-5366.

Sincerely,

Dennis Lawyer

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MESSAGE

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Options

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