From: Lawyer, Dennis
To: radcor@sbcglobal.net
Subject: Pfizer, Inc., Request for Additional Information Concerning Application for a License Renewal, Control 584532
Date: Wednesday, October 22, 2014 2:43:00 PM

Dear Mr. David Durkee,

This is in reference to your application dated August 1, 2014, requesting for amendment to Nuclear Regulatory Commission License No. 06-05869-01, Docket No. 03003790. In order to continue our review, we need the following additional information:

1) Your renewal application did not request to continue the preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72 and for non-medical use to authorized recipients. Please state that you no longer need this authorized use or provide information as stated in the guidance of NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," Appendix U.

2) You have lowered the maximum amount you may possess on the license. Many of the isotopes you have lowered to or below your atomic number 1-83 broadscope authorization per radionuclide amount. It is recommended to remove the isotope line items for those isotopes that are at or below your broadscope per radionuclide authorization. This would eliminate 5 specific isotopes from you license and avoid confusion with the broadscope authorization. Adjustment would also need to be made to the Certification of Financial Assurance.

3) In the section describing you Radiation Policy Committee, it states that a minimum of fifty percent of the total committee membership present at a meeting will constitute a quorum. This statement is somewhat confusing. It would appear you mean: A quorum is established when fifty percent or more of all committee members are present. Please make this statement or a clearly state the requirements for a quorum.

4) You requested to make program changes. In NUREG-1556, Volume 11, section 8.7.2, Radiation Safety Committee, states to provide a description of the process for procedure and program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change. It did not appear that you stated how the changes were documented. Please state where the approval of the changes will be documented and that it will include the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change.

5) In section 8 of your application, you describe training requirements. In NUREG-1556, Volume 11, section 8.8, it states, to submit a description of the radiation safety training program developed for each group of workers, including: topics covered; qualifications of the instructors; method of training; method for

assessing the success of the training; and the frequency of training and refresher training. You application did not appear to state what a qualified instructor needs to meet and what the method for assessing the success of the training performed. Please state, what you consider a qualified instructor and what method for assessing the success of the training performed.

6) On October 9th, the termination of NRC License No. 06-05869-03 was completed. This will make significant changes to the Decommissioning Funding Plan and Financial Assurance Documents. It is recommended that you make the changes to the Decommissioning Cost Estimate, Certification of Financial Assurance, and your financial instruments as a result of the license termination.

7) The Decommissioning Funding Plan dated August 1, 2014, used:
   a. 2013 prices to obtain an estimate. The estimate should be of current prices. Please use current prices in the cost estimate.
   b. made the assumption that analytical survey instrumentation possessed by Pfizer, Inc. would be utilized. The cost should be based on an independent contractor performing the decommissioning as stated in 10 CFR 30.35(e)(1)(i)(A).
   c. did not state that a detailed cost estimate would be re-performed at least every three years as required in 10 CFR 30.35(e)(2). Please make this statement.
   d. did not state the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination as required by 10 CFR 30.35(e)(1)(i)(C) . Please make this statement.

   Guidance for a Decommissioning Funding Plan can be found in NUREG-1757, Volume 3, Revision1, "Consolidated Decommissioning Guidance, Financial Assurance, Recordkeeping and Timeliness."

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office (Address below) and refer to Mail Control No. 584532. If you have technical questions regarding this letter, please call me at (610) 337-5366.

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). Please respond within 30 calendar days from the date of this e-mail.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-2713.

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