From: Tran, Frank
To: thockemeyer@pointbiopharma.com
Subject: RE: NRC license application dated May 28, 2020
Date: Thursday, July 23, 2020 11:04:00 AM
Attachments: NUREG-1556 Vol 7 Rev1 ML18065A006.pdf
NRC Memo Licensing of Lutetium177.pdf
Curium.pdf

Dear Mr. Hockemeyer:

Based on a discussion with you this morning via telephone, you stated that you may consider to apply for a research and development license at this time. You stated that you will review the applicable licensing guidance and regulations and will provide a response next week.

Please review NUREG-1556, Volume 7, Revision 1 for preparation for the response. As you mentioned that your company plans to manufacture and distribute radioactive drugs containing byproduct material for medical use under 10 CFR part 35, please review 10 CFR 32.72 for relevant NRC requirements for such license. Here is a link to 10 CFR 32.72: https://www.nrc.gov/reading-rm/doc-collections/cfr/part032/. A copy of NUREG-1556, Volume 7, Revision 1 is also attached for your reference. In addition, you may find some useful information related to your application at the following links.

- NRC application fee: https://www.nrc.gov/reading-rm/doc-collections/cfr/part170/
- NRC annual fee: https://www.nrc.gov/reading-rm/doc-collections/cfr/part171/
- Product Manufacturing and Distribution of Radioactive Material: https://www.nrc.gov/materials/miau/product-manufac.html

You also asked for a copy of the NRC license for Curium. For your information, NRC License No. 13-35179-02 is available for the public which you can obtain from the NRC public website (a copy of the license is attached for your convenience).

In the application, you request for 1526 curies of Lu-177. Based on the NRC memorandum regarding the licensing of Lu-177, the quantity of Lu-177m may be 0.02% of total amount of Lu-177. Therefore, your possession limit of Lu-177m may be up to 305.2 millicuries. Based on 10 CFR 30.35 and Appendix B to part 30, Lu-177m is not listed in the table and therefore the default value of 0.1 microcurie for radioisotope other than alpha emitting should be used. Based on your requested quantity for Lu-177 and Ge-68/Ga-68 generators, you meet the criteria in 10 CFR 30.35. Please provide information required by 10 CFR 30.35 or reduce the possession limit to below the threshold listed in 10 CFR 30.35.

Please remember to date and sign your correspondence.

Sincerely,

Frank Tran

From: Tran, Frank

Sent: Friday, July 17, 2020 5:37 PM
To: thockemeyer@pointbiopharma.com
Subject: NRC license application dated May 28, 2020

Dear Mr. Hockemeyer:

This references to your application dated May 28, 2020 for a new NRC license and a telephone conference with you on July 17, 2020.

Based on Item 6, “Purpose for Use of Radioactive Material”, it appeared that the application is for authorization of radioactive material for testing of the new facilities and for research and development of drugs before submitting to the FDA for approval.

However, the application which was prepared using NUREG-1556, Volume 12, stated that it is for radiopharmaceutical manufacturing and distribution. In addition, during the telephone conversation you also restated that the applicant planed to make drugs for medical use and will distribute directly to other authorized licenses (hospitals, clinics, authorized users, etc.)

Based on the NRC licensing guidance, commercial radiopharmacy licenses are those licenses issued by the NRC, pursuant to Title 10 of the Code of Federal Regulations (10 CFR) Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” and 10 CFR 32.72, “Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.” If you would like to apply for a radiopharmacy license which authorizes for the distribution of nuclear medicine, you should use the guidance in NUREG-1556, Volume 13, Revision 2, “Program-Specific Guidance About Commercial Radiopharmacy Licenses”. A copy of this guidance is attached for your reference.

The application requests for the use of Germanium-68/Gallium-68 generators. Also, it requests for a large quantity of Lutetium-177 which generates a long half-life daughter isotope Lu-177m. Based on the unsealed long half-life isotopes, you provided a description of the decommissioning plan. In the decommissioning plan, you assumed that all licensed material will be intact and will be returned to the manufacturers and the waste onsite will be disposed by transferring to other authorized licenses. This plan does not appear to align with the NRC decommissioning assumptions. One of the NRC conservative assumption is the facilities including equipment where the isotopes in questions had been used were contaminated and the decommissioning cost estimate will include the cost for radiation assessment, planning, cleaning, disposing, radiation surveying, etc. Please review 10 CFR 30.35, NUREG-1757, Volume 3, and the attached Ge-68/Ga-68 generator licensing guidance, for regulatory requirements and licensing guidance related to decommissioning financial assurance. You could find a copy of NUREG-1757, Volume 3 on the NRC’s website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/.

At this time, we want to understand what type of NRC license you would like to apply for. If you would like to pursue a research and development license at this time in preparation for submitting the drugs to the FDA for approval as indicated in the application and will pursue a commercial radiopharmaceutical production and distribution after the drugs were approved by the FDA, please let us.

I apology that our call was accidently disconnected during our telephone conference today. If you have any question, please feel free to reply to this email or call me at 630-829-9623.

Best regards,

Frank Tran
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