From: Tran, Frank
To: thockemeyer@pointbiopharma.com
Subject: NRC license application dated May 28, 2020
Date: Friday, July 17, 2020 5:37:00 PM
Attachments: NUREG-1556_Vol 13_Rev 2_ML19079A207.pdf
Ge-68 Ga-68 licensing guidance July 2019.pdf
Ge-68_Ga-68 generator DFA memo_ML17075A487.pdf

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,

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