



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

March 8, 2017

Jason J. Wilson, R.Ph.
Radiation Safety Officer
Radiopharmacy Incorporated
1409 E. Virginia St.
Evansville, IN 47711

Dear Mr. Wilson:

This concerns the December 7, 2016 letter (ML16343A951), submitted by Richard L. VanSant, Pharm.D., Director of Regulatory Affairs, PharmaLogic Holdings Corp. In that letter, Mr. VanSant requested to add an authorization for the possession and use of germanium-68/gallium-68 (Ge-68/Ga-68) generators to your NRC License No. 13-26246-01MD. Via electronic mail on January 27, 2017, I transmitted a letter to both you and Mr. VanSant, requesting additional information necessary to complete our review. Although Mr. VanSant – via letters dated January 31 and February 8, 2017 – provided a partial response to our request, additional information is still needed for us to complete our review. As stated in our January 27, 2017 letter, we cannot add an authorization for possession and use of germanium-68, absent additional information, including required financial assurance and a signed and dated legally binding agreement for the return and acceptance of returned generators between Radiopharmacy Incorporated, NRC License No. 13-26246-01MD and the generator manufacturer, Eckert & Ziegler.

To resubmit your request, please send a signed and dated cover letter, addressed to our office, attention "Materials Licensing Branch," attaching documentation including:

- (1) Radionuclide, form, possession limit, and use information for each requested radionuclide, including total number of generators and confirmation that the requested use authorization is specific to the E&Z GalliaPharm™ generator, and that use is limited to the preparation of Ga-68 radiopharmaceuticals for imaging and localization studies. When resubmitting, please follow the U.S. Nuclear Regulatory Commission (NRC) licensing guidance document, "Eckert and Ziegler GalliaPharm™ Germanium-68/Gallium-68 Pharmacy Grade Generator," dated October 17, 2016 (ML16287A403), as applicable to commercial nuclear pharmacy use.
- (2) A facility diagram, drawn to scale, that describes where generator(s) will be received, used, and stored, and indicates a brief description (i.e. cafeteria, offices, restrooms, inaccessible roof, etc.) of uses above, below, and adjacent to the Ge-68/Ga-68 use area.
- (3) Commitments and statements in accordance with the above-referenced NRC licensing guidance document, including confirmation that the licensee will develop and implement written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's 0.001 percent breakthrough limit, i.e., the presence of Ge-68 in excess of a ratio of 0.01 μ Ci Ge-68 per mCi Ga-68.

- (4) Confirmation that the licensee is not requesting authority to update Radiation Protection Programs, absent a license amendment incorporating such changes.
- (5) If not submitting a Decommissioning Funding Plan (DFP) in support of the application:
 - (a) Confirmation that the licensee is requesting an exemption from the 10 CFR 30.35(a)(1) requirement that an applicant for a license to use and possess Ge-68/Ga-68 generators must submit a Decommissioning Funding Plan (DFP) together with financial assurance determined from the DFP; and
 - (b) Copy of a legally binding agreement between the licensee and the manufacturer that the licensee will return – and the manufacturer will accept – generators if they are expired, are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals; and

NOTE: Any such agreement must be signed, with legible names, titles, and signature dates.

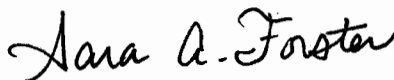
- (c) Under separate cover letter, original Financial Assurance (FA) certification based on possession limit, as required by 10 CFR 30.35 –
 - (i) For up to two generators and up to 100 millicuries total, FA in the amount of \$225,000; or
 - (ii) For three to twenty generators and up to 1 curie total, FA in the amount of \$1,125,000.

NOTE: For additional guidance, please refer to Appendix A, "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning" of NUREG-1757, Volume 3, revision 1, "Financial Assurance, Recordkeeping, and Timeliness."

You may resubmit your request via regular mail or via facsimile to (630) 515-1078. If you have any questions concerning this letter, please do not hesitate to call me at the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9892.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS, which is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Sara A. Forster, M.S.
Health Physicist
Materials Licensing Branch