UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 6, 2017

Richard L. Van Sant, Pharm.D.
Director of Regulatory Affairs
PharmaLogic Ltd.
1191 S. Brownell Road, Suite 40
Williston, VT 05495

SUBJECT: PHARMALOGIC LTD., VOIDANCE OF YOUR REQUEST FOR AMENDED LICENSE, MAIL CONTROL NO. 592537, AND LICENSE AMENDMENT, MAIL CONTROL NO. 592895

Dear Dr. Van Sant:

This refers to your license amendment requests dated December 7, 2016 and January 26, 2017. Please find enclosed Amendment No. 32 authorizing Steven C. Green, R.Ph. as an authorized nuclear pharmacist (ANP). Because you informed us that you are not currently able to provide the additional information required to add the Eckert and Ziegler GalliaPharm Germanium-68/Gallium-68 pharmacy grade generator, we have voided your request. This action is taken without prejudice to the resubmission of your request. If you wish to resubmit your request to add the Eckert and Ziegler GalliaPharm Germanium-68/Gallium-68 pharmacy grade generator, you may resubmit your application in whole or reference Mail Control No. 592537 and provide the following additional information:

1. Via memo dated July 29, 2016 (ML16082A415), NRC's Office of Nuclear Material Safety and Safeguards (NMSS) authorized the NRC Region I Office to grant specific exemptions from the 10 CFR 30.35(a)(1) DFP requirement noted above. As noted in the memo, our office may grant such an exemption provided that the application provides documentation:

   (i) Demonstrating that a legally binding agreement is in place for the licensee to return the generators to the manufacturer or distributor when the generators expire and are no longer used to prepare Ga-68 radiopharmaceuticals for patients, or if the licensee ceases its preparation of Ga-68 radiopharmaceuticals; that legally binding agreement between the licensee and generator manufacturer or distributor must highlight licensee commitments to return expired generators back to the manufacturer or distributor and also must include a manufacturer or distributor commitment to take expired generators back; and

   (ii) Including Financial Assurance (FA) certification based on possession limit –

      a. For up to two generators and up to 100 millicuries total, FA amount is $225,000; or
      b. For three to twenty generators and up to 1 curie total, FA amount is $1,125,000.

Our review of the above-referenced letter and the additional information submitted on February 10, 2017, which included a revised agreement with Eckert and Ziegler (E&Z), indicated the following:

(i) Although it contained a copy of a return agreement between PharmaLogic and E&Z, that agreement was not dated. Accordingly, please submit a legally binding agreement between the manufacturer and the licensee. At a minimum, in addition to information already contained in the submitted agreement, the document should:

a. Be signed and dated by either you or other duly authorized representative of PharmaLogic Ltd.; and

b. Be co-signed and dated by a duly-authorized E&Z representative, including a legibly printed or typed name and title.

(ii) To date, no FA has been submitted on behalf of PharmaLogic Ltd., on behalf of the licensee's request to receive, use, and possess Ge-68/Ga-68 generators. The NRC Region I office cannot issue a Ge-68/Ga-68 generator authorization prior to receipt and review of FA documents, as required by 10 CFR 30.35.

Accordingly, please submit the financial assurance documents required by 10 CFR 30.35. The amount of FA to be submitted would be based on the number of generators possessed. For instance, licensees possessing more than 2 and up to 20 Ge-68 generators (with an estimated activity of >100 to 1000 mCi) would be subject to the requirement in § 30.35(d) for a minimum $1,125,000 in financial assurance for the decommissioning of site(s). Licensees possessing one or two Ge-68 generators (50 to 100 mCi) would be subject to a $225,000 FA minimum. 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." Checklist 1 in Section A.4 may be helpful for determining the mechanism that will be used and the supporting documents that require submission. FA must be in place and complete prior to amending the NRC license for possession of this material.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5006 or via electronic mail at janice.nguyen@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at: http://www.nrc.gov/reading-rm/doc-collections/enforcement/.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding medical uses of radioactive materials may be obtained on the NRC Web Site at: http://www.nrc.gov/materials/miau/med-use-toolkit.html. This site also provides the updated Training and Experience NRC Form 313A series of forms and guidance, as well as information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: http://www.nrc.gov/about-nrc/safety-culture.html. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: http://www.nrc.gov/reading-rm/adams.html.

Thank you for your cooperation.

Sincerely,

/RA/

Janice Nguyen, Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
Region I

License No. 44-30124-01MD
Docket No. 030-33449
Mail Control Nos. 592537 and 592895

Enclosure:
Amendment No. 32

cc: Zonker White, R.Ph.,
Radiation Safety Officer

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/RA/

Janice Nguyen, Senior Health Physicist
Medical Branch
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Radiation Safety Officer

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SUNSI Review Complete: JNguyen
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