

From: [Nguyen, Janice](#)
To: [Reid Gadziala](#)
Subject: NRC Request for Additional Information for PharmaLogic WV, Ltd. (Mail Control Number 613727)
Date: Tuesday, August 06, 2019 11:30:00 AM

Licensee: PharmaLogic WV, Ltd.
License No.: 47-25375-01MD
Docket No.: 030-34289
Control No.: 613727

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Dear Dr. Gadziala:

This is in reference to your letter dated July 24, 2019, requesting to amend Nuclear Regulatory Commission License No. 47-25375-01MD. With regard to your request to add a new manufacturer of Germanium-68/Gallium-68 generator, the IRE Galli-Eo, please provide the following additional information:

1. Please confirm if you wish to be authorized for all manufacturers of Germanium-68/Gallium-68 pharmaceutical grade generators.
2. If you replied yes to question 1, please commit to the following statements regarding each manufacturer of Ge-68/Ga-68 generator, in accordance with the revised "Germanium-68/Gallium-68 Pharmaceutical Grade Generators Licensing Guidance" dated July 2019:
 - We will develop and implement written procedures for the determination of breakthrough that will detect whether the eluate exceeds the manufacturer's recommended breakthrough limit; and
 - During the course of breakthrough testing, if the eluate exceeds the manufacturer's breakthrough limits, the eluate will not be distributed or administered to a patient or human research subject.

We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management and scanned into a pdf format), or fax (610-337-5269), referencing mail control number 613727. Please submit a reply within 30 days of the date of this email, or we will assume you no longer wish to pursue this amendment. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

Thank you in advance for your help!

Sincerely,

Jan

Janice Nguyen
Senior Health Physicist
U.S. Nuclear Regulatory Commission
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406
Office (610) 337-5006
FAX (610) 337-5269