



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

August 18, 2021

Reid Gadziala  
Vice President, Pharmacy Operations  
PharmaLogic Puerto Rico  
150 Federico Costa Street, Suite 1  
San Juan, PR 00918-1303

**SUBJECT:** SUSPENSION OF REVIEW OF AMENDMENT REQUEST DATED MAY 20, 2021 FOR PHARMALOGIC PUERTO RICO, NRC LICENSE NO. 52-25361-01MD, MAIL CONTROL NO. 625815

Dear Mr. Gadziala:

We have reviewed your letter dated May 20, 2021 requesting an amendment to your U.S. Nuclear Regulatory Commission (NRC) license. You have requested the use of Germanium-68/Gallium-68 generators which requires \$225,000 in financial assurance. You submitted an incomplete financial assurance package on June 2, 2021, which was controlled under Control No. 627093. Your application for Control No. 625815 is available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession No. ML21144A082, and your application for Control No. 627093 is available electronically from ADAMS at Accession No. ML21179A228.

Based on the review, our office determined that additional financial assurance documentation under Control No. 627093 was needed from you to approve your request under Control No. 625815. Accordingly, we prepared and sent you a written request for additional information via e-mail dated June 25, 2021. As discussed subsequently via e-mails dated July 20, 2021 and August 9, 2021, and via telephone conversation dated August 11, 2021, the application is lacking additional information. To date, we are still missing the Model Specimen Certificate of Events (unsigned), Model Specimen Certificate of Resolution (unsigned), and the Certification of Financial Assurance. In our conversation, you indicated that you needed additional time to gather, prepare, and submit the requested information. Accordingly, as discussed, we have suspended review of your application pending receipt of the additional requested information. Due to the delay in receiving the additional requested information that is necessary for the approval of your amendment request, the NRC cannot project when it will make a determination on the amendment request. Once a complete response is received, the NRC will provide an updated date for the NRC to complete its review. If an adequate response is not received by September 30, 2021, the NRC will administratively close or deny the request, as appropriate.

Note that if your request is administratively closed, you may submit a new request at a later date and refer to Control No. 625815 for the documentation you have already submitted.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

If you have any questions, please contact me at (610) 337-5006 or [janice.nguyen@nrc.gov](mailto:janice.nguyen@nrc.gov).

Thank you for your cooperation.

Sincerely,

Janice Nguyen, Senior Health Physicist  
Medical and Licensing Assistance Branch  
Division of Radiological Safety and Security  
Region I

License No. 52-25361-01MD

Docket No. 030-34187

Mail Control No. 625815

cc: Rolando Garcia, R.Ph., BCNP, Radiation Safety Officer

SUSPENSION OF REVIEW OF AMENDMENT REQUEST DATED MAY 20, 2021 FOR PHARMALOGIC PUERTO RICO, NRC LICENSE NO. 52-25361-01MD, MAIL CONTROL NO. 625815 DATED AUGUST 18, 2021

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**SUNSI Review Complete: JNguyen**

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DATE	8/18/2021		8/18/2021					

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