



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

June 28, 2021

Gerard Strugala, R.Ph., BCNP
Vice President, Quality & Regulatory
PharmaLogic Puerto Rico
150 Federico Costa, Suite 1
San Juan, PR 00918-1303

SUBJECT: PHARMALOGIC PUERTO RICO, LICENSE AMENDMENT, MAIL CONTROL
NO. 626831

Dear Mr. Strugala:

This refers to your license amendment request dated April 22, 2021. Please find enclosed Amendment No. 6 changing the name of the license, following the previously approved change of control of the license.

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) 337-5040 or by electronic mail to Elizabeth.Ullrich@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.

NRC's Regulatory Issue Summary (RIS) 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31, and in accordance with 10 CFR 2.390, this letter and the enclosed license document are exempt from public disclosure because their disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC Web Site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security-related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

Thank you for your cooperation.

Sincerely,

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License Nos. 52-25361-02
Docket No. 030-38114
Mail Control No. 626831

Enclosure:
Amendment No. 6

cc: Rolando Garcia, R.Ph., BCNP, Radiation Safety Officer
Eduardo Diaz-Montes, R.Ph., BCNP, Senior Operations Manager

PHARMALOGIC PUERTO RICO, LICENSE AMENDMENT, MAIL CONTROL NO. 626831
DATED JUNE 28, 2021

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SUNSI Review Complete: Betsy Ullrich

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