

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, ILLINOIS 60532-4352

November 26, 2023

James P. Nunn, M.S., CHP Corporate Radiation Safety Officer PharmaLogic Holdings, Inc. 5301 North Federal Highway Suite 280 Boca Raton, FL 33487

Dear James P. Nunn:

Enclosed is Amendment No. 12 to your NRC Material License No. 24-32762-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

Or please contact me at <a href="mailto:colleen.casey@nrc.gov">colleen.casey@nrc.gov</a> or (630) 829-9841. My fax number is 630-515-1078.

We did not receive Mr. Hall's contact information, including his telephone number, email address and fax number.

In a future amendment, please provide this information to us using the NRC Form 313 or equivalent, currently dated and signed by a senior management representative.

In your letter dated August 16, 2023, in item 1.c. you stated that: "A discussion and interview regarding Mr. Hall's experience and training was held with a Region III representative on 5, July 2023 to support this change."

A Teams call was held on July 5, 2023, with Dr. Andrew Borrok, Mr. Hall you and me. It is rather mis-characterized in your assertions above to imply that I subjectively spoke about and considered Mr. Hall's application. I did not do so.

I asked many questions to discern Mr. Hall's qualifications appropriately because his initial application in the letter dated April 20, 2023, was incorrect and misleading. There was no "interview" of any sort.

The call with me was not conducted to "support" your requested change in the Radiation Safety Officer (RSO). It was done to request additional information to be provided in the correct format with information required by our regulations and appropriate guidance.

## J. Nunn

Please kindly refrain from such assumptions and conclusions in the future.

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 Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

You will be periodically inspected by 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 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 General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

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 <a href="http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html">http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</a>.

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.

If you have any questions, please contact me at 630-829-9841 or <a href="mailto:colleen.casey@nrc.gov">colleen.casey@nrc.gov</a>. Contacting me via email is the most reliable method.

Sincerely,

Colleen Carol Casey Health Physicist Materials Licensing Branch

License No. 24-32762-01MD Docket No. 030-38129