

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 2100 RENAISSANCE BOULEVARD, SUITE 100 KING OF PRUSSIA, PA 19406-2713

## November 18, 2014

Docket No. 03033449 License No. 44-30124-01MD

Control No. 584038

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

SUBJECT: PHARMALOGIC LTD., LICENSE RENEWAL, CONTROL NO. 584038

Dear Dr. Van Sant:

This refers to your request for renewal of your NRC license. Enclosed with this letter is the renewed license. 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 I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the serious consequences to employees and the public that can result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application. In particular, note that you must:

- 1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
- 2. Notify the NRC in writing of any change in mailing address.
- 3. In accordance with 10 CFR 30.36(d), notify the NRC, promptly, in writing, and request termination of the license
  - a) when you decide to terminate all activities involving materials authorized under the license; or
  - b) if you decide not to acquire or possess and use authorized material.
- 4. Request and obtain a license amendment before you:
  - a) change Radiation Safety Officers;

- b) order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
- c) add or change the areas of use, or addresses of use identified in the license application or on the license; or
- d) change the name or ownership of your organization.
- 5. Submit a complete renewal application or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations.

You will be periodically inspected by the NRC. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and the 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, imposition of a civil penalty, or an order suspending, modifying or revoking your license.

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

Current NRC regulations and guidance are included on the NRC's website at <a href="www.nrc.gov">www.nrc.gov</a>; 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).

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/safety-culture.html">http://www.nrc.gov/about-nrc/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.

Thank you for your cooperation.

Sincerely,

Original signed by Penny Lanzisera

Penny Lanzisera Senior Health Physicist Medical Branch Division of Nuclear Materials Safety

Enclosure:

Amendment No. 28

CC:

Richard Sucese, R.Ph., Radiation Safety Officer

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**SUNSI Review Complete:** JNguyen

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