REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 4, 2009

Docket No. 03033449 License No. 44-30124-01MD
Control No. 143481

Thomas DeFranco, R.Ph.
Radiation Safety Officer
PharmaLogic LTD.
9 Krupp Drive
P.O. Box 786
Williston, VT 05495

SUBJECT: PHARMALOGIC LTD., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 143481

Dear Mr. DeFranco:

This is in reference to your letter dated March 1, 2009 requesting to amend Nuclear Regulatory Commission License No. 44-30124-01MD and your additional information letter dated April 27, 2009. In order to continue our review, we need the following additional information:

1. You have requested additional pharmaceuticals. Please confirm that radiopharmaceuticals will be prepared under the supervision of an ANP or will be obtained from a supplier authorized pursuant to 10 CFR 32.72, or under equivalent Agreement State requirements; and describe all licensed material to be distributed or redistributed.

2. Your additional information letter requested to add brachytherapy sources as listed in 10 CFR 35.400 to your list of authorized materials. Per NUREG-1556, Volume 13, Revision 1, Section 8.6.1, please confirm that:

    a. you plan to redistribute the brachytherapy sources;

    b. the sealed sources for brachytherapy to be redistributed will be obtained from a manufacturer authorized to distribute sealed sources for brachytherapy in accordance with a specific licensed issued pursuant to 10 CFR 32.74, or under equivalent Agreement State requirements; and

    c. the manufacturer's packaging, labeling, and shielding will not be altered and that redistributed sources will be accompanied by the manufacturer-supplied package insert, leaflet, brochure, or other document that provides radiation safety instructions for handling and storing the sources.

3. The maximum radiation level at transport shield surface for fluorine 18 does not appear to meet the guidance as stated in NUREG-1556, Volume 13, Revision 1, Section 8.10.12. It states that approval has been given for diagnostic dosages up to 50 mrem/hr. Please consider another alternative for the transportation shield.

4. The transport shield surface readings for samarium 153, strontium 89, and rubidium 81/krypton 81 as “to be determined” is not satisfactory. You may calculate the anticipated maximum shield surface reading or determine from others experience.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** 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 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 143481. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5366.

If we do not receive a reply from you within 15 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Elizabeth Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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SUNSI Review Complete: DLawyer

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