



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

August 22, 2012

Docket No. 03034289
Control No. 577444

License No. 47-25375-01MD

Glenn Palmer, R.Ph.
PharmaLogic WV Ltd.
109 Platinum Drive, Suite A
Bridgeport, WV 26330

SUBJECT: PHARMALOGIC WV LTD., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO.
577444

Dear Mr. Palmer:

This is in reference to the application dated April 26, 2012 requesting to renew Nuclear Regulatory Commission License No. 47-25375-01MD. In order to continue our review, we need the following additional information:

1. Your renewal application requests Glenn Palmer be named as the Radiation Safety Officer (RSO) on the license. However, subsequent to your renewal application you also requested an amendment to the license to replace Glenn Palmer with Teresa Tribe as the RSO and which became effective in Amendment No. 18. Please confirm that Teresa Tribe will continue to be the RSO on this license.
2. You included copies of the Nuclear Pharmacy Permits issued by the West Virginia Board of Pharmacy to the Bridgeport and Barboursville, WV locations. The permits expired on June 30, 2012. Please submit copies of the new permits which became effective July 1, 2012.
3. In Attachment 9.3, page 5, paragraph 6.a of both the Bridgeport and the Barboursville facilities descriptions, you state, "The sampling system consists of a vacuum pump with two continuously-running (24 hours per day) air flow gauges reading in CFM." Please provide information on the frequency and method for calibration of the air flow gauges.
4. You provided sample copies of product labels to be used. Please confirm that you agree to affix the required labels to all "transport radiation shields" and each container used to hold the radioactive drugs (per item 10.11 of Appendix D, NUREG-1556, Vol. 13, Rev.1).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; 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).

We will continue our review upon receipt of this information. Please reply to my attention at the

G. Palmer

2

Region I Office and refer to Mail Control No. 577444. If you have any technical questions regarding this deficiency letter, please call Todd Jackson at (610)337-5308 or me at (610) 337-5040.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Please note that the office of the Region I Division of Nuclear Materials Safety has moved effective May 9, 2012. Our new address is:

U. S. Nuclear Regulatory Commission
Region I
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

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/regulatory/enforcement/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

Sincerely,

Original signed by Elizabeth Ullrich

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

cc:

Teresa Tribe, R.Ph., Radiation Safety Officer

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SUNSI Review Complete: TJackson

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