UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

November 2, 2007

Docket No. 03034289 License No. 47-25375-01MD
Control No. 141093

Gerard Strugala, R.Ph.
Vice President, Operations
Pharmalogic WV, Ltd.
109 Platinum Drive, Suite A
Bridgeport, WV 26330

SUBJECT: PHARMALOGIC WV, LTD., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 141093

Dear Mr. Strugala:

This is in reference to your application dated September 1, 2007 requesting to amend Nuclear Regulatory Commission License No. 47-25375-01MD. In order to continue our review, we need the following additional information:

1. Currently, Glen Plamer, R.Ph., is listed as the management contact. Do you wish to change the management contact to Gerald Strugala, R.Ph.?

2. F-18, I-111, I-123, and Tl-201 produced in a cyclotron is currently not subject to licensing by the NRC. Therefore, you may procure and use it without amendment to your NRC material license. However, you should contact your State regulatory authorities to determine the State licensing or registration requirements for use of this radionuclide. No reply is needed on this item.

3. On Attachment 5.1, you requested a maximum amount of material of analytical samples, “as needed.” Our current guidance does not allow using “as needed” maximum amounts for this material. Please specify the maximum amount or control the amount under the broad classification of byproduct material with atomic number 1-83.

4. Attachment 5.1 gives the amount of material requested for the additional location. Please request the total amount of material requested for both pharmacies.

5. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; **or** contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed source(s) requested in your application. Please subdivide the list into each category of distribution (i.e. 35.400, 35.500, 35.65(a)). Ensure the distribution and possession manufacturer’s and model numbers are supplied for both locations.

6. Attachment 5.1 item 17, requests any byproduct material authorized under 35.57(a). Please confirm that this is a request for any byproduct material authorized under 35.65(a).

7. Attachment 5.1, item 18, requests for Cs-137 source for instrumentation calibration. Is this the same as the listed sources in Attachment 5.2? If so, why is this line item in addition to line item 17?

8. As stated in Section 8.6.2 of NUREG-1556 Volume 13, 'Program-Specific guidance About Commercial Radiopharmacy Licenses', the applicant should indicate the types of radiopharmaceutical preparation activities it intends to perform (e.g. compounding of iodine-131 capsules, radioiodination, and technetium-99m kit preparation).

9. As stated in Section 8.6.4 of NUREG-1556 Volume 13, the applicant must submit specific procedures for all service activities that it intends to provide. Please submit procedure for leak testing.

10. Attachment 6.4 and 9.3c appears to incorrectly calculate a sample pump flow of 0.46 CFM to 22640 ml/min. Please correct spreadsheet and resubmit.

11. Attachment 9.3c includes the Ba-133 calibration cartridge correction to I-131. There appears to be an inaccuracy being applied. If the window of the instrument is set at 309 KeV, then the gamma energy of 303 would generally not be counted. Secondly, the worksheet in Attachment 6.4 and 9.3c uses a multiplication factor of 1.11. By the calculation presented it should be divided by 1.11 as the I-131 intensity is less than the overall Ba-133 intensity. Please review and correct.

12. Please confirm that you will not use alpha emitting radioactive drugs.

13. Attachment 10.4 lists the radioactive drug shielding for distribution. Some of the drugs do not have the maximum radiation level at transport shield surface. Please complete this table.

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 8:00 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. 141093. If you have any technical questions regarding this deficiency letter, please call Dennis Lawyer at (610) 337-5366 or me at (610) 337-5303.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Glen Palmer, R.Ph., Radiation Safety Officer

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SUNSI Review Complete: DLawyer
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