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

January 22, 2007

Docket No. 030-34289 License No. 47-25375-01MD
Control No. 139921

Glen Palmer, R.Ph.
Radiation Safety Officer
Pharmalogic WV, Ltd.
109 Platinum Drive
Suite A
Bridgeport, WV 26330

SUBJECT: PHARMALOGIC WV, LTD., LICENSE AMENDMENT, CONTROL NO. 139921

Dear Mr. Palmer:

This refers to your license amendment request. Enclosed with this letter is the amended license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. 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.

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 www.nrc.gov; select **Nuclear Materials; Medical, Industrial, and Academic Uses of Nuclear Material;** then **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

Original signed by Bryan A. Parker

Bryan A. Parker
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 09

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	In accordance with the letter dated January 2, 2007,
1. Pharmalogic WV, Ltd.	3. License No. 47-25375-01MD is amended in its entirety to read as follows:
2. 109 Platinum Drive Suite A Bridgeport, West Virginia 26330-2007	4. Expiration Date: May 31, 2012
	5. Docket No. 030-34289

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Any byproduct material with atomic numbers 3 through 83, except molybdenum-99, technetium-99m, iodine-131 and xenon-133	A. Any	A. 600 millicuries per radionuclide and 1 curie total
B. Molybdenum 99	B. Any	B. 100 curies
C. Technetium 99m	C. Any	C. 100 curies
D. Xenon 133	D. Any	D. 1 curie
E. Iodine 131	E. Any	E. 1500 millicuries
F. Any byproduct material in a brachytherapy source as permitted by 10 CFR 35.400	F. Sealed source	F. 500 millicuries
G. Any byproduct material in a sealed source for diagnosis as permitted by 10 CFR 35.500	G. Sealed source	G. 1.5 curies per source and 5.5 curies total
H. Any byproduct material listed in 10 CFR 31.11(a)	H. Prepackaged units for *in vitro* diagnostic tests	H. 50 millicuries
I. Any byproduct material authorized under 10 CFR 35.65(a)	I. Sealed source	I. 50 millicuries
J. Yttrium 90	J. Any	J. 100 millicuries

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.
47-25375-01MD

Docket No.
030-34289

Amendment No.
09

9. Authorized use:

A. through E. Preparation and distribution of radioactive drugs, production of technetium 99m pertechnetate, compounding of iodine 131 and distribution of unused and used molybdenum 99/technetium 99m generators to authorized recipients in accordance with 10 CFR 32.72 and to authorized recipients for non-medical use.

F. and G. Redistribution of sealed sources to authorized recipients in accordance with 10 CFR 32.74 and to authorized recipients for non-medical use.

H. Redistribution to specific licensees or general licensees pursuant to 10 CFR 31.11 provided the packaging and labeling remain unchanged

I. Calibration and checking of the licensee's instruments. Redistribution of sealed sources initially distributed by a manufacturer licensed pursuant to 10 CFR 32.74 to authorized recipients and to authorized recipients for non-medical use.

J. For preparation and distribution as IDEC-Y2B8 radioimmunotherapy of relapsed or refractory, low-grade or follicular transformed B-cell Non-Hodgkin's Lymphoma as permitted by FDA multicenter, open label trial under Study Protocol No. IDEC 106-98, under IND No. BB IND 4850-IDEC-Y2B8/IDEC-In2B8.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 109 Platinum Drive, Suite A, Bridgeport, West Virginia.

11. Licensed material shall be used by, or under the supervision of:

A. A pharmacist working or designated as an authorized nuclear pharmacist in accordance with 10 CFR 32.72(b)(2)(i) or (4);

B. Authorized nuclear pharmacists: Glen Palmer, R.Ph., William M. Chatoff, R.Ph., Thomas Defranco, R.Ph., Jeffrey Letendre, R.Ph., Christopher Leon, R.Ph., Dave Lamont, R.Ph., Todd Landry, R.Ph., Jack Kolacz, R.Ph., Shawn P. Lorrain, R.Ph., Elliot Rosario-Santos, R.Ph., or Joel A. Cordero-Rivera, R.Ph.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.
47-25375-01MD

Docket No.
030-34289

Amendment No.
09

12. The Radiation Safety Officer (RSO) for this license is Glen Palmer, R.Ph.

13. In addition to the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

14. This license does not authorize commercial distribution of licensed material to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.21, inclusive, or equivalent regulations of any Agreement State.

15. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed six months or at the intervals specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

    D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

    E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U. S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.
47-25375-01MD

Docket No.
030-34289

Amendment No.
09

G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U. S. Nuclear Regulatory Commission or an Agreement State to perform such services.

H. Records of leak test results shall be kept in units of microcuries and shall be maintained for five years.

16. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee, except as specifically authorized.

17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U. S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for five years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.

18. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and

B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and

C. Maintains records of the disposal of licensed materials for three years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. The licensee is authorized to retrieve, receive and dispose of radioactive waste from it's customers limited to radiopharmacy supplied syringes and vials and their contents.

20. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE SUPPLEMENTARY SHEET

License No.
47-25375-01MD

Docket No.
030-34289

Amendment No.
09

21. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Application dated July 1, 1996
B. Letter dated August 12, 1996
C. Letter dated October 14, 1996
D. Letter dated November 14, 1996
E. Letter dated February 11, 1997 [ML030770843]
F. Letter dated February 24, 1997 [ML030770839]
G. Letter dated March 4, 1997 [ML030770828]
H. Letter dated March 6, 1997 [ML030770834]
I. Letter dated June 15, 1998 [ML030770817]
J. Letter dated March 21, 2000 [ML003694946]
K. Letter dated January 30, 2001 [ML010390311]
L. Letter dated May 4, 2001 [ML011290352]
M. Letter dated June 4, 2001 [ML011570496]
N. Letter dated August 28, 2001 [ML012500043]
O. Application dated December 5, 2001 [ML013410308]
P. Letter dated December 18, 2002 [ML023570443]
Q. Letter dated January 24, 2006 [ML060240178]

For the U. S. Nuclear Regulatory Commission

Date January 22, 2007

By ***Original signed by Bryan A. Parker***

Bryan A. Parker
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406