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

January 23, 2007

Docket No. 03035882 License No. 29-30698-01
Control No. 139960

Mathew L. Swan, C.I.H.
Director, Environment, Health & Safety/ Radiation Safety Officer
Purdue Pharma L.P.
6 Cedarbrook Drive
Cranbury, NJ 08512

SUBJECT: PURDUE PHARMA L.P., LICENSE AMENDMENT, CONTROL NO. 139960

Dear Mr. Swan:

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, Academic, and Industrial 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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Thank you for your cooperation.

Sincerely,

***Original signed by Thomas K. Thompson***

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

Enclosure:
Amendment No. 9

DOCUMENT NAME: C:\FileNet\ML070260651.wpd

**SUNSI Review Complete:** TThompson
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| NAME | TThompson ***/TKT/*** | | | | | | | |
| DATE | 1/23/07 | | | | | | | |

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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 | |
|---|---|
| 1. Purdue Pharma, L.P. | In accordance with the letter dated January 9, 2007,<br>3. License No. 29-30698-01<br>is amended in its entirety to read as follows: |
| 2. 6 Cedarbrook Drive<br>Cranbury, New Jersey 08512 | 4. Expiration Date: January 31, 2012 |
| | 5. Docket No. 030-35882 |

| 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. Hydrogen 3 | A. Any | A. 100 millicuries |
| B. Carbon 14 | B. Any | B. 50 millicuries |
| C. Phosphorus 32 | C. Any | C. 10 millicuries |
| D. Phosphorus 33 | D. Any | D. 10 millicuries |
| E. Sulfur 35 | E. Any | E. 70 millicuries |
| F. Chromium 51 | F. Any | F. 20 millicuries |
| G. Yttrium 90 | G. Any | G. 50 millicuries |
| H. Iodine 125 | H. Bound to non-volatile agents | H. 20 millicuries |
| I. Iodine 131 | I. Bound to non-volatile agents | I. 50 millicuries |

9. Authorized use:

A. - I. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 6 Cedarbrook Drive, Cranbury, New Jersey.

**MATERIALS LICENSE SUPPLEMENTARY SHEET**

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11. A. Licensed material in Items 6.A. through 6.I. shall be used by, or under the supervision of, Greg Crumley. Licensed material in 6.A., 6.B., 6.D., 6.E., 6.F., 6.H., and 6.I. shall be used by, or under the supervision of, Wendy Miller and Aniket Patel.

    B. The Radiation Safety Officer (RSO) for this license is Mathew L. Swan.

12. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

13. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

14. The licensee shall conduct a physical inventory every six months, or at other interval approved by the U. S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.

15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

16. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 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. 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.

    C. 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.

    D. 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.

    E. 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.

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F. Tests for leakage and/or contamination, limited to leak test sample collection, 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. The licensee is not authorized to perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

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

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

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. 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 November 19, 2001 [ML013370499]
B. Letter dated January 2, 2002 [ML020020303]
C. Letter dated January 16, 2002 [ML020240022]
D. Letter dated December 2, 2002 [ML023380346]
E. Letter dated December 21, 2004 [ML050060404]
F. Letter dated January 11, 2005 [ML050330069]
G. Letter dated December 6, 2005 [ML053470452]

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For the U. S. Nuclear Regulatory Commission

Date January 23, 2007

By ***Original signed by Thomas K. Thompson***

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406