



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

November 30, 2004

Docket No. 03019868
Control No. 135922

License No. 29-21169-01

Robert J. Broeze, Ph.D.
President
Laureate Pharma, Inc.
201 College Road East
Princeton, NJ 08540

SUBJECT: LAUREATE PHARMA, INC., ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 135922

Dear Dr. Broeze:

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).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

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

Enclosure:
Amendment No. 16

R. Broeze
Laureate Pharma, Inc.

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cc:
Paul M. Kaladas, Ph.D., Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML043360101.wpd

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DATE	11/30/04		11/30/04					

OFFICIAL RECORD COPY

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.

<p style="text-align: center;">Licensee</p> <p>1. Laureate Pharma, Inc.</p> <p>2. 201 College Road East Princeton, New Jersey 08540-6610</p>	<p>In accordance with the letter dated October 29, 2004,</p> <p>3. License number 29-21169-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date February 28, 2005</p> <hr/> <p>5. Docket No. 030-19868 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. As specified in Section 33.100, Schedule A, of 10 CFR 33 (Type C Broad License)</p> <p>B. Yttrium 90</p> <p>C. Iodine 125</p> <p>D. Iodine 131</p> <p>E. Samarium 153</p> <p>F. Cesium 137</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Sealed Source (E.I. duPont Model NES-356)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. See Condition 12</p> <p>B. 1 curie</p> <p>C. 200 millicuries</p> <p>D. 1 curie</p> <p>E. 1 curie</p> <p>F. 209 microcuries</p>
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9. Authorized use:

A. through F. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 201 College Road East, Princeton, New Jersey.

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11. A. Licensed material shall be used by or under the supervision of individuals designated in writing by the Radiation Safety Officer.
- B. The Radiation Safety Officer for this license is Paul M. Kaladas, Ph.D.
12. A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column II. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.
- B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column II, the applicable quantities for the following radionuclides are reduced to:
- | | |
|---|-----------------|
| Carbon 14 | 100 millicuries |
| Krypton 85 | 100 millicuries |
| Iodine 129 | 100 microcuries |
| Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A | 100 microcuries |
13. Licensed material shall not be used in or on human beings.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
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.

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- 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.
- F. 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.
17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
18. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.
20. This license does not authorize commercial distribution of licensed material.
21. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:
- A. Waste to be disposed of in this manner shall be held for decay a minimum of ten half-lives.
- B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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- C. A record of each such disposal permitted under this License Condition shall be retained for three years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.
- 22. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
- 23. 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 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 September 28, 1993
 - B. Letter dated January 30, 1995
 - C. Facsimile dated February 8, 1995



For the U.S. Nuclear Regulatory Commission

Date November 30, 2004
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By ***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich
 Commercial and R&D Branch
 Division of Nuclear Materials Safety
 Region I
 King of Prussia, Pennsylvania 19406