



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

March 16, 2005

Docket No. 03030473
Control No. 136303

License No. 29-28169-01

Kathleen Monroe
Vice President of Operations
Synaptic Pharmaceutical Corporation
215 College Road
Paramus, NJ 07652-1431

SUBJECT: SYNAPTIC PHARMACEUTICAL CORPORATION, ISSUANCE OF LICENSE
AMENDMENT, CONTROL NO. 136303

Dear Ms. Monroe:

This refers to your license amendment request. Enclosed with this letter is the amended license. When performing surveys for release of laboratories, you must keep records of the survey results, survey methods and the instrumentation used, including minimum detectable activity. These records may be reviewed during inspection. You are also required to maintain these records, which may be important for decommissioning, for all areas where NRC licensed material has been used in accordance with 10 CFR 30.35(g).

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 available at the NRC Web sites listed below or 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 David B. Everhart

David B. Everhart
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 13

K. Monroe
Synaptic Pharmaceutical Corporation

2

NRC Web site addresses

NRC regulations

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Licensing guidance

<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>

General Policy and Procedure for NRC Enforcement Actions

<Http://www.nrc.gov/what-we-do/regulatory/enforcement/enforc-pol.pdf>

206 of the Energy Reorganization Act of 1974

<http://www.nrc.gov/who-we-are/governing-laws.html>

cc:

Halim A Hasan, Radiation Safety Officer

K. Monroe
Synaptic Pharmaceutical Corporation

3

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NAME	DEverhart/DBE							
DATE	3/16/2005							

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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.

<p>Licensee</p> <p>1. Synaptic Pharmaceutical Corporation</p> <p>2. 215 College Road Paramus, New Jersey 07652-1431</p>	<p>In accordance with the letter dated January 14, 2005,</p> <p>3. License number 29-28169-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date October 31, 2013</p> <p>5. Docket No. 030-30473 Reference No.</p>
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| <p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Phosphorus 33</p> <p>E. Sulfur 35</p> <p>F. Iodine 125</p> <p>G. Iodine 129</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. Any</p> <p>G. Sealed source</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 500 millicuries</p> <p>B. 40 millicuries</p> <p>C. 200 millicuries</p> <p>D. 200 millicuries</p> <p>E. 350 millicuries</p> <p>F. 400 millicuries</p> <p>G. 3 microcuries</p> |
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9. Authorized use:

- A. through F. Research and development as defined in 10 CFR 30.4; animal studies.
- G. Calibration and checking of the licensee's instruments.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at 215 College Road, Paramus, New Jersey and 170 Williams Drive, Ramsey, New Jersey.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-28169-01Docket or Reference Number
030-30473

Amendment No. 13

11. A. Licensed material shall be used by, or under the supervision of, Roman Artymyshyn, Carlos Forray, M.D., Christophe Gerald, Ph.D., Halim A. Hasan, Kelli Smith, or Mary W. Walker, Ph.D.
- B. Licensed material in items 6.A., 6.B., 6.E., and 6.F. shall be used by, or under the supervision of, Douglas Craig, or Margaret Durkin.
- C. The Radiation Safety Officer for this license is Halim A. Hasan.
12. Licensed material shall not be used in or on human beings.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
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 is authorized to hold radioactive material with a physical half-life of less than or equal to 120 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.
- 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.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-28169-01Docket or Reference Number
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Amendment No. 13

17. 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. Letter dated February 9, 1998
- B. Letter dated March 30, 1998
- C. Letter dated August 21, 2000 (ML003744091)
- D. Letter dated February 16, 2001 (ML010650297)
- E. Letter dated September 26, 2003 (ML032751189)
- F. Letter dated September 1, 2004 (ML042530537)
- G. Letter dated January 14, 2005 (ML050320438)



For the U.S. Nuclear Regulatory Commission

Date March 16, 2005By ***Original signed by David B. Everhart***

David B. Everhart
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406