



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

January 5, 2005

Docket No. 03033707
Control No. 136018

License No. 37-30182-01

Jason Van Buren
Senior Director, Operations and Planning
3-Dimensional Pharmaceuticals, Inc.
Eagleview Corporate Center
665 Stockton Drive, Suite 104
Exton, PA 19341

SUBJECT: 3-DIMENSIONAL PHARMACEUTICALS, INC., ISSUANCE OF LICENSE
AMENDMENT, CONTROL NO. 136018

Dear Mr. Van Buren:

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

Carl Crysler is authorized to use, or supervise the use of, iodine-125 and tritium, radionuclides with which he has previous experience. The other radionuclides listed on your license have different radiation and energies than those of either iodine-125 or tritium. He may use the other radionuclides under the supervision of another authorized user, and when he has sufficient experience with the other types of radionuclides, you may request to have him approved as an authorized user of those materials.

In accordance with NRC Regulatory Issue Summary (RIS) 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material (<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417.pdf>), your license has been modified. Your license now contains a revised decay-in-storage (DIS) condition. This revised condition permits greater flexibility for DIS of waste by eliminating a specific holding period prior to disposal. Please review the RIS 2004-17, and the revised condition carefully to ensure that you understand its requirements.

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

J. Van Buren
3-Dimensional Pharmaceuticals, Inc.

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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

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

Enclosure:
Amendment No. 12

DOCUMENT NAME: E:\Filenet\ML050070134.wpd

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DATE	1/5/05							

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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. 3-Dimensional Pharmaceuticals, Inc. A wholly owned subsidiary of Johnson & Johnson</p> <p>2. Eagleview Corporate Center 665 Stockton Drive, Suite 104 Exton, Pennsylvania 19341</p>	<p>In accordance with the letter dated November 12, 2004,</p> <p>3. License number 37-30182-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date May 31, 2010</p> <p>5. Docket No. 030-33707 Reference No.</p>	
<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>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. Labeled compounds</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 75 millicuries</p> <p>B. 40 millicuries</p> <p>C. 50 millicuries</p> <p>D. 25 millicuries</p> <p>E. 50 millicuries</p> <p>F. 50 millicuries</p>
<p>9. Authorized use:</p> <p>A. through F. Research and development as defined in 10 CFR 30.4.</p>		

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at 665 Stockton Drive, Suite 104, Exton, Pennsylvania, and Cedarbrook Corporate Center, 8 Clarke Drive, Cranbury, New Jersey.

**MATERIALS LICENSE
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11. A. Licensed material shall be used by, or under the supervision of, Alexander N. Barnakov, Christian Baumann, Margery A. Chaikin, Carl Manthey, Dionisios Rentzeperis or Jason Van Buren. Licensed material listed in Items 6.A. and 6.F. may also be used by, or under the supervision of, Carl Crysler.
- B. The Radiation Safety Officer for this license is Jason Van Buren.
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. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
- 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 3 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.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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16. 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. Letter dated December 4, 2002



For the U.S. Nuclear Regulatory Commission

Original signed by Elizabeth Ullrich

Date January 5, 2005

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By

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