



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

March 23, 2005

Docket No. 03036411  
Control No. 136447

License No. 37-30839-01

Gerard M. McGeehan  
Vice President, Discovery Biology  
Vitae Pharmaceuticals  
502 West Office Center Drive  
Fort Washington, PA 19034

SUBJECT: VITAE PHARMACEUTICALS, ISSUANCE OF LICENSE AMENDMENT,  
CONTROL NO. 136447

Dear Mr. McGeehan:

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 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. 1

G. McGeehan  
Vitae Pharmaceuticals

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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:

Richard K. Harrison, Ph.D., Radiation Safety Officer

G. McGeehan  
Vitae Pharmaceuticals

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|--------|---------------|---|---------|--|---------|--|--|--|
| OFFICE | DNMS/RI       | N | DNMS/RI |  | DNMS/RI |  |  |  |
| NAME   | DEverhart/DBE |   |         |  |         |  |  |  |
| DATE   | 3/23/2005     |   |         |  |         |  |  |  |

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.

|  |   |
|--|---|
| Licensee   | in accordance with the letter dated<br>February 7, 2005                         |
| 1. Vitae Pharmaceuticals   | 3. License number 37-30839-01 is amended<br>in its entirety to read as follows: |
| 2. 502 West Office Center Drive<br>Fort Washington, Pennsylvania 19034 | 4. Expiration date October 31, 2013   |
|  | 5. Docket No. 03036411<br>Reference No.   |

- |   |                                  |  |
|---|----------------------------------|--|
| 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. 20 millicuries  |
| B. Carbon 14  | B. Any                           | B. 20 millicuries  |
| C. Phosphorus 32                                      | C. Any                           | C. 50 millicuries  |
| D. Phosphorus 33                                      | D. Any                           | D. 50 millicuries  |
| E. Sulfur 35  | E. Any                           | E. 20 millicuries  |
| F. Iodine 125   | F. Non-volatile Compounds        | F. 20 millicuries  |

## 9. Authorized use:

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

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 502 West Office Center Drive, Fort Washington, Pennsylvania.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
37-30839-01Docket or Reference Number  
03036411

Amendment No. 1

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

Authorized UsersMaterial

Richard Harrison, Ph.D.

Hydrogen-3, Carbon-14, Phosphorous-32,  
Phosphorous-33, Sulfur-35, Iodine-125

Yuri Bukhtiyarov, Ph.D.

Hydrogen-3, Carbon-14, Phosphorous-32,  
Phosphorous-33, Sulfur-35

Jennifer Mason

Hydrogen-3, Carbon-14, Sulfur-35, Iodine-125

Boyd Scott, Ph.D.

Hydrogen-3, Carbon-14, Phosphorous-32,  
Phosphorous-33, Sulfur-35

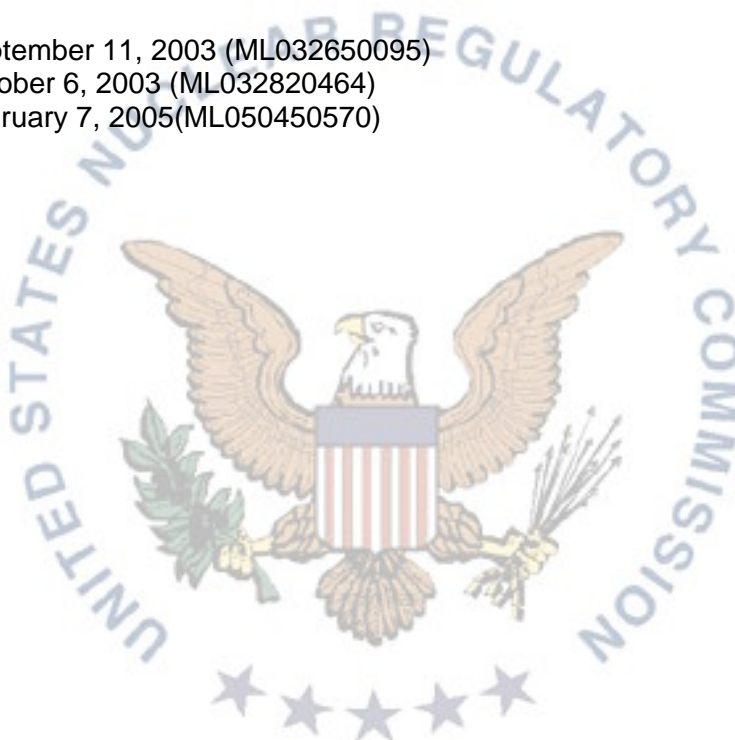
- B. The Radiation Safety Officer for this license is Richard Harrison, Ph.D..

12. The licensee shall not use licensed material in or on human beings.
13. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
14. 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 10 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 3 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.
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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Amendment No. 1

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 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 September 11, 2003 (ML032650095)
  - B. Letter dated October 6, 2003 (ML032820464)
  - C. Letter dated February 7, 2005 (ML050450570)



For the U.S. Nuclear Regulatory Commission

Date March 23, 2005

By

***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