



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

June 17, 2005

Docket No. 03019666  
Control No. 137150

License No. 29-21016-01

Ronald S. Levy, Ph.D.  
Executive Vice President  
Unigene Laboratories, Inc.  
110 Little Falls Road  
Fairfield, NJ 07004-2193

SUBJECT: UNIGENE LABORATORIES, INC., LICENSE AMENDMENT, CONTROL NO.  
137150

Dear Dr. Levy:

This refers to your license amendment request. Enclosed with this letter is the amended license. As discussed during our telephone conversation on June 17, 2005, in the interest of expediting your amendment request, the license was amended to allow only the use of iodine-125 in the form of radioimmunoassay kits at the Boonton, New Jersey facility. Should you wish to expand the use of licensed materials at this facility, you will need to submit another request that describes the specific facilities and equipment that you will have in place at the facility to permit the safe use of these materials. In addition, you requested that Jeffrey Neubig, Ph.D. be named Radiation Safety Officer (RSO) for the new facility. Please be advised that NRC policy requires that each license have only one RSO. You may delegate RSO functions at the Boonton facility to Dr. Neubig; however, you may not delegate RSO responsibilities.

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 site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/who-we-are/governing-laws.html> 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).

R. Levy  
Unigene Laboratories, Inc.

2

Thank you for your cooperation.

Sincerely,

***Original signed by James P. Dwyer***

James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

Enclosure:  
Amendment No. 8

R. Levy  
Unigene Laboratories, Inc.

3

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NAME	JDwyer/JPD1							
DATE	6/17/2005							

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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. Unigene Laboratories, Inc.</p> <p>2. 110 Little Falls Road Fairfield, New Jersey 07004-2193</p>	<p>In accordance with the letter dated June 3, 2005,</p> <p>3. License number 29-21016-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date October 31, 2014</p> <p>5. Docket No. 030-19666 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. Calcium 45</p> <p>G. Chromium 51</p> <p>H. 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. Any</p> <p>G. Any</p> <p>H. Any</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 100 millicuries</p> <p>B. 40 millicuries</p> <p>C. 25 millicuries</p> <p>D. 50 millicuries</p> <p>E. 50 millicuries</p> <p>F. 5 millicuries</p> <p>G. 10 millicuries</p> <p>H. 20 millicuries</p> |
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## 9. Authorized use:

A. through H. Research and development as defined in Section 30.4 of 10 CFR Part 30; animal studies.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License Number  
29-21016-01Docket or Reference Number  
030-19666

Amendment No. 8

**CONDITIONS**

10. Licensed material may be used or stored only at the licensee's facilities located at 110 Little Falls Road, Fairfield, Essex County, New Jersey. Licensed material in Item 6.H, in the form of radioimmunoassay kits, may also be used or stored at the licensee's facilities located at 83 Fulton Street, Boonton, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, Ronald S. Levy, Nozer M. Mehta, Duncan A. Miller, Martha Ray, William Stern, or Amy M. Sturmer. Licensed material listed in Item 6. A through 6.E. shall be used by, or under the supervision of, Angelo Consalvo or Christopher Meenan. Licensed material in Item 6.H, in the form of radioimmunoassay kits, shall be used by, or under the supervision of Jeffrey Neubig, Ph.D..
- B. The Radiation Safety Officer for this license is Ronald S. Levy.
12. The licensee shall not use licensed material in or on human beings.
13. This license does not authorize commercial distribution of licensed material.
14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
15. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
16. 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.
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."

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18. 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 September 14, 2004  
B. Letter dated June 3, 2005



For the U.S. Nuclear Regulatory Commission

Date June 17, 2005

By

***Original signed by James P. Dwyer***

James P. Dwyer, Chief  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406