

U.S. NUCLEAR REGULATORY COMMISSION

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. Department of Health and Human Services U. S. Food and Drug Administration Center for Drug Evaluation and Research Office of Testing and Research Division of Drug Safety Research</p> <p>2. Life Sciences Building #64, Room 2022 10903 New Hampshire Avenue Silver Spring, Maryland 20993</p>	<p>In accordance with the letter dated June 24, 2011,</p> <p>3. License number 19-07538-05 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2015</p> <hr/> <p>5. Docket No. 030-31689</p> <hr/> <p>Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3 B. Carbon 14 C. Sulfur 35</p>	<p>7. Chemical and/or physical form</p> <p>A. Any B. Any C. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 90 millicuries B. 80 millicuries C. 10 millicuries</p>
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9. Authorized use:

A. through C. Research and development as defined in 10 CFR 30.4; animal studies.

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at the Life Sciences Building #64, 10903 New Hampshire Avenue, Silver Spring, Maryland.
11. Licensed material shall be used by, or under the supervision of, Donna Volpe, Ph.D., Neil Hartman, Ph.D., Aspandiar S. Katki, Robert Parker, Ph.D., and Edward Radden.
12. The Radiation Safety Officer for this license is Neil Hartman, Ph.D.
13. The licensee shall not use licensed material in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-05Docket or Reference Number
030-31689

Amendment No. 13

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 byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
 - 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.
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 June 10, 2005 [ML051780367]
 - B. Letter dated September 23, 2005 [ML052730133]



For the U.S. Nuclear Regulatory Commission

Date June 29, 2011

By

Original signed by Thomas K. Thompson

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406