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

June 6, 2005

Docket No. 03036120 License No. 19-30771-01
Control No. 136383

Arnold P. Borsetti, Ph.D.
Associate Director for Operations
Center for Food Safety and Applied Nutrition
Department of Health and Human Services
Food and Drug Administration
Harvey W. Wiley Building, HFS 003
5100 Paint Branch Parkway
College Park, MD 20740

SUBJECT: CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, APPLICATION FOR LICENSING ACTION, CONTROL NO. 136383

Dear Dr. Borsetti:

This refers to your license amendment request. Enclosed with this letter is the amended license. The facility at Federal Building 8 (FB8) located at 200 C Street SW, Washington, DC may be released for unrestricted use.

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.

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).

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. 3

cc:
Constance S. Rosser, Radiation Safety Officer

DOCUMENT NAME: G:\Docs\Mailed\Lic Cvr Letter\l19-30771-01.136383.06072005.wpd

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DATE	6/6/2005							

OFFICIAL RECORD COPY

Amendment No. 3

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	
1. Department of Health & Human Services Food and Drug Administration	In accordance with the letter received January 31, 2005, 3. License number 19-30771-01 is amended in its entirety to read as follows:
2. Harvey W. Wiley Building, HFS 003 5100 Paint Branch Parkway College Park, Maryland 20740	4. Expiration date April 30, 2005 (extended) 5. Docket No. 030-36120 Reference No. 08-00482-03/030-03917

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. Any byproduct material specified in 10 CFR 33.100, Schedule A	A. Any	A. As specified in 10 CFR 33.100, Schedule A, Column I, subject to Condition 12 of this license

9. Authorized use:

A. 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 Muirkirk Road Complex, Laurel, Maryland, and may be used at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

11. A. Licensed material shall be used by or under the supervision of individuals designated, in writing, by the Radiation Safety Officer.

    B. The Radiation Safety Officer for this license is Constance Sims Rosser.

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12. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

13. The licensee shall not use licensed material in or on human beings.

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. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.

    B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.

    C. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

    D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

    E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

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G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

17. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.

18. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license.

19. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

20. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.

B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

21. 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.

22. Radioactive waste possessed under this license shall be stored in accordance with the statements, representations, and procedures included with the licensee's waste storage plan described in the letter dated November 4, 1994.

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23. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

24. 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 November 4, 1994
B. Application dated November 29, 1994
C. Letter dated January 3, 1995
D. Letter dated March 3, 1995
E. Letter dated March 23, 1995
F. Letter dated July 16, 1996
G. Letter dated September 9, 1999
H. Letter dated September 5, 2002 [ML022600636]
I. Letter dated November 21, 2002 [ML023260398]
J. Letter dated November 25, 2002 [ML023300264]
K. Letter dated December 17, 2003 [ML033580332]
L. Letter dated January 8, 2004 [ML040220636]
M. Letter dated January 23, 2004 [ML040430126]
N. Letter dated June 17, 2004 [ML041810150]

For the U.S. Nuclear Regulatory Commission

Date June 7, 2005

By ***Original signed by Elizabeth Ullrich***

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