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

June 12, 2001

Docket No. 03033524 License No. 37-01531-07
Control No. 129714

Edwin Wurtz, Ph.D.
Director, Health Physics, BioSafety
& Environmental Affairs
Merck & Co., Inc.
P.O. Box 4, WP 42-210
Sumneytown Pike
West Point, PA 19486-0004

SUBJECT: MERCK & CO., INC., ISSUANCE OF LICENSE AMENDMENT, CONTROL NO. 129714

Dear Dr. Wurtz:

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

The enclosed amended license (Amendment No. 9) is written in a format that incorporates current U.S. Nuclear Regulatory Commission requirements and policy. One condition that appeared in Amendment No. 8 of your license was revised and one condition was deleted. 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.

In accordance with 10 CFR 2.790, a copy of this letter will be placed in the NRC Public Document Room and will be accessible from the NRC Web site at http://www.nrc.gov/NRC/ADAMS/index.html.

Thank you for your cooperation.

Sincerely,

Original signed by Pamela J. Henderson

Pamela J. Henderson
Senior Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosure:
Amendment No. 9

cc:

6/22

John J. Miller, Radiation Safety Officer

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NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 9

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. Merck & Co., Inc.	In accordance with the letter dated April 30, 2001, 3. License number 37-01531-07 is amended in its entirety to read as follows:
2. P.O. Box 4, WP 42-210 Sumneytown Pike West Point, Pennsylvania 19486	4. Expiration date June 30, 2005 5. Docket No. 030-33524 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. Any byproduct material with atomic numbers 1 through 83	A. Any	A. 50 millicuries per radionuclide and 1 curie total
B. Hydrogen 3	B. Any	B. 20 curies
C. Carbon 14	C. Any	C. 2 curies
D. Phosphorus 32	D. Any	D. 250 millicuries
E. Phosphorus 33	E. Any	E. 200 millicuries
F. Sulfur 35	F. Any	F. 5 curies
G. Calcuim 45	G. Any	G. 100 millicuries
H. Chromium 51	H. Any	H. 600 millicuries
I. Technetium 99m	I. Any	I. 500 millicuries
J. Iodine 125	J. Any	J. 1 curie
K. Xenon 133	K. Any	K. 500 millicuries
L. Cesium 137	L. Any	L. 1 curie
M. Americium 241	M. Any	M. 3 millicuries
N. Molybdenum 99 / Technetium 99m	N. Generators	N. 4 curies

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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
O. Hydrogen 3	O. Plated sources or foils	O. 200 millicuries per foil and 1 curie total
P. Nickel 63	P. Plated sources or foils	P. 15 millicuries per source and 1 curie total
Q. Iodine 125	Q. Sealed sources (Amersham Model IMC.P2)	Q. 300 millicuries per source and 1200 millicuries total
R. Cesium 137	R. Sealed sources (Amersham Model No.77302)	R. 150 millicuries per source and 600 millicuries total
S. Gadolinium 153	S. Sealed sources (Lunar Model GD series)	S. 1500 millicuries per source and 3 curies total

9. Authorized use:

A. through N. Research and development as defined in 10 CFR 30.4; animal studies; manufacture of labelled compounds and transfer of the compounds to individuals authorized to receive the material by the terms and conditions of a specific license issued by the U.S. Nuclear Regulatory Commission or any Agreement State.

O. through P. In electron capture detector cells which are distributed under a specific license issued by the U.S. Nuclear Regulatory Commission or by any Agreement State.

Q. For use in Lunar Model SP2 Bone Mineral Analyzer for non-human use.

R. For use in Amersham Model 773 Instrument Calibrator for calibration of instruments.

S. For use in Lunar Model DP3 or DP4 Bone Mineral Analyzer for non-human use.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities located at Sumneytown Pike, West Point, Pennsylvania; 502 and 503 Louise Lane, North Wales, Pennsylvania; and 466 Devon Park Drive, Wayne, Pennsylvania.

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

B. The Radiation Safety Officer for this license is John J. Miller.

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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. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.

15. Notwithstanding 10 CFR 33.17(a)(4), the licensee is authorized to manufacture drugs containing radioactive material for distribution to specific licensees.

16. Replacement-exchange of the Lunar Bone Mineral Analyzer's source/source-holder combination may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual.

17. 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. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.

    D. 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.

    E. 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.

    F. 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.

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G. 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.

H. 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.

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

19. The licensee shall conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

20. 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.

21. 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.

22. 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 ten 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.

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C. A record of each such disposal permitted under this License Condition shall be retained for three 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.

23. Radioactive waste generated shall be stored in accordance with the statements, representations, and procedures included with the waste storage plan described in the licensee's letters dated October 11, 1994 and February 22, 1995.

24. Pursuant to 10 CFR 20.1302(c) and 10 CFR 20.2002, the licensee is authorized to dispose of licensed material by incineration provided the gaseous effluent from incineration does not exceed the limits specified for air in 10 CFR Part 20, Appendix B.

25. Pursuant to 10 CFR 20.2002, the licensee may dispose of incinerator ash containing radioactive materials with atomic numbers 1 through 83, except the radionuclides identified below, as ordinary waste in a landfill provided the concentration of the radionuclides (in microcuries per gram of ash) at the time of disposal are no greater than the values in Table II, Column 2, 10 CFR Part 20, Appendix B. For hydrogen-3, carbon-14, aluminum-26, chlorine-36, silver-108m, niobium-94, iodine-129, technetium-99, and thallium-204, the concentration can be no greater than one-tenth of the value in Table II, Column 2, 10 CFR Part 20, Appendix B.

26. 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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27. 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 March 21, 1994
B. Letter dated October 11, 1994
C. Letter dated February 22, 1995
D. Letter dated May 10, 1995
E. Letter dated June 2, 1995
F. Letter dated June 7, 1995
G. Letter dated June 13, 1995
H. Letter dated August 21, 1995
I. Letter dated April 4, 1997
J. Letter dated June 6, 1997
K. Letter dated September 26, 1997
L. Letter dated December 7, 1998
M. Letter dated November 30, 1999
N. Letter dated April 30, 2001

For the U.S. Nuclear Regulatory Commission

Date June 12, 2001

By *Original signed by Pamela J. Henderson*

Pamela J. Henderson
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406