



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

October 11, 2001

Docket No. 03005222
Control No. 130090

License No. 29-00139-02

Susan Voigt
Chair, Radiation Safety Committee, Senior Director
E. R. Squibb & Sons, Inc.
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903-0191

SUBJECT: E. R. SQUIBB & SONS, INC., ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 130090

Dear Ms. Voigt:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that you must prepare radioactive drugs in accordance with an accepted U.S. Food and Drug Administration Investigational New Drug application protocol and you must comply with all other applicable sections of 10 CFR 32.72.

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

S. Voigt
E. R. Squibb & Sons, Inc.

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Enclosure:
Amendment No. 99

cc:
Michael J. Vala, C.H.P., Radiation Safety Officer

S. Voigt
E. R. Squibb & Sons, Inc.

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	PHenderson/PJH1							
DATE	10/11/2001							

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 1. E. R. Squibb & Sons, Inc. 2. 311 Pennington-Rocky Hill Road Mail Stop HW8T-1.12 Pennington, New Jersey 08534-2130	In accordance with the letter dated July 18, 2001, 3. License number 29-00139-02 is amended in its entirety to read as follows: 4. Expiration date September 30, 2008 5. Docket No. 030-05222 Reference No.	
6. Byproduct, source, and/or special nuclear material A. Any byproduct material with atomic numbers 1 through 83, except Strontium 90 B. Iodine 131 C. Hydrogen 3 D. Carbon 14 E. Strontium 90 F. Technetium 99m G. Any byproduct material with atomic numbers 84 through 103 H. Nickel 63 I. Any byproduct material with atomic numbers 1 through 83, except Strontium 90 J. Hydrogen 3	7. Chemical and/or physical form A. Any B. Any C. Any D. Any E. Any F. Any G. Any H. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State. I. Any J. Any	8. Maximum amount that licensee may possess at any one time under this license A. 100 millicuries per radionuclide and 2 curies total B. 2 curies C. 20 curies D. 20 curies E. 2 millicuries F. 750 millicuries G. 1 millicurie H. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State I. 200 millicuries per radionuclide and 6 curies total J. 7 curies

MATERIALS LICENSE SUPPLEMENTARY SHEET

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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 |
| K. Carbon 14 | K. Any | K. 5 curies |
| L. Phosphorus 33 | L. Any | L. 1 curie |
| M. Sulfur 35 | M. Any | M. 10 curies |
| N. Iodine 125 | N. Any | N. 500 millicuries |
| O. Nickel 63 | O. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State | O. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State |
| P. Any byproduct material with atomic numbers 1 through 83, except, Strontium 90 | P. Any | P. 200 millicuries per radionuclide and 6 curies total |
| Q. Hydrogen 3 | Q. Any | Q. 500 millicuries |
| R. Carbon 14 | R. Any | R. 500 millicuries |
| S. Sulfur 35 | S. Any | S. 300 millicuries |
| T. Calcium 45 | T. Any | T. 300 millicuries |
| U. Nickel 63 | U. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State | U. No single source to exceed the maximum activity specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State |
| V. Any byproduct material with atomic numbers 1 through 83, except Strontium 90 | V. Any | V. 10 millicuries per radionuclide and 1 curie total |
| W. Hydrogen 3 | W. Any | W. 100 millicuries |
| X. Carbon 14 | X. Any | X. 100 millicuries |
| Y. Sulfur 35 | Y. Any | Y. 300 millicuries |
| Z. Phosphorous 32 | Z. Any | Z. 100 millicuries |

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6. Byproduct, source, and/or special
nuclear material

AA. Phosphorous 33

BB. Iodine 125

CC. Nickel 63

7. Chemical and/or physical form

AA. Any

BB. Any

CC. Foil or plated sources
registered either with the
U.S. Nuclear Regulatory
Commission under
10 CFR 32.210 or with an
Agreement State8. Maximum amount that licensee may
possess at any one time under this
license

AA. 200 millicuries

BB. 50 millicuries

CC. No single source to exceed
the maximum activity
specified in the certificate of
registration issued by the
U.S. Nuclear Regulatory
Commission or an
Agreement State

9. Authorized use:

A., C., D., E., and G. Research and development as defined in 10 CFR 30.4; animal studies; and calibration and checking of the licensee's instruments.

B. and F. Research and development as defined in 10 CFR 30.4; animal studies.

C. and D. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72.

I. through N., P. through T., and V. through BB. Research and development as defined in 10 CFR 30.4; animal studies; and calibration and checking of the licensee's instruments.

H., O., U., and CC. To be used for sample analysis in compatible gas chromatography devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and have been distributed in accordance with a Commission or Agreement State specific license authorizing distribution to persons specifically authorized by a Commission or Agreement State license to receive, possess, and use the devices.

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CONDITIONS

10. A. Licensed material in Items 6.A. through 6.H. may only be used at the licensee's facilities located at One Squibb Drive, New Brunswick, New Jersey.
- B. Licensed material in Items 6.I. through 6.O. may only be used at the licensee's facilities located at Route 206 and Provinceline Road, Lawrenceville, New Jersey.
- C. Licensed material in Items 6.P. through 6.U. may only be used at the licensee's facilities located at 311 Pennington-Rocky Hill Road, Pennington, New Jersey.
- D. Licensed material in Items 6.V. through 6.CC. may only be used at the licensee's facilities located at Three Hamilton Health Place, Hamilton, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee.
- B. The Radiation Safety Officer for this license is Michael J. Vala, CHP.
12. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.
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. Experimental animals administered licensed materials or their products shall not be used for human consumption.
15. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or equivalent regulations of any Agreement State or to persons exempt from licensing pursuant to 10 CFR 30.14 through 30.20 inclusive, or equivalent regulations of any Agreement State.
16. This license does not authorize commercial distribution of licensed material.
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.

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- 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.
- 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, or at other interval approved by the U.S. Nuclear Regulatory Commission, to account for all sealed sources and/or devices received and possessed under the license.

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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 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.
- 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.
22. The licensee shall submit a revised Decommissioning Funding Plan that includes all licensed locations and activities, by March 1, 2003 or ninety days following completion of the decommissioning of building 124 at the New Brunswick, New Jersey location, whichever occurs earlier. The Decommissioning Funding Plan shall be sent to the Director, Division of Nuclear Materials Safety, Region I Office referenced in Appendix D of 10 CFR Part 20.
23. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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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 March 23, 1992
- B. Letter dated May 8, 1992
- C. Letter dated February 17, 1994
- D. Letter dated June 20, 1994
- E. Application dated February 18, 1997
- F. Letter dated August 26, 1997
- G. Letter dated August 29, 1997
- H. Letter dated October 15, 1997
- I. Letter dated June 19, 1998
- J. Letter dated August 19, 1998
- K. Letter dated March 15, 2001
- L. Letter dated May 15, 2001
- M. Letter dated July 18, 2001, except decommissioning plan
- N. Letter dated October 2, 2001

For the U.S. Nuclear Regulatory Commission

Date October 11, 2001

By

Original signed by Pamela J. Henderson

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