



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

January 26, 2005

Docket No. 03005222
Control No. 136051

License No. 29-00139-02

Louis Fedele
Vice President, Facilities
E. R. Squibb & Sons
Bristol-Myers Squibb Company
Technical Operations, Worldwide Medicines Group
Route 206 & Provinceline Road
Lawrenceville, NJ 08543

SUBJECT: E. R. SQUIBB & SONS, ISSUANCE OF LICENSE AMENDMENT, CONTROL
NO. 136051

Dear Mr. Fedele:

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

As part of this amendment of your license, the license conditions were updated in accordance with current standard conditions. Obsolete conditions were removed from your license. In addition, Items 6, 7 and 8 were revised to list nickel-63 sealed sources (Item 6.G.) only once, rather than listing this radionuclide, form, and limit four times; and Item 6.G. is authorized in License Condition 10 for use at each of the four locations.

In accordance with NRC Regulatory Issue Summary (RIS) 2004-17: Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material (<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417.pdf>), your license has been modified. Your license now contains a revised decay-in-storage (DIS) condition. This revised condition permits greater flexibility for DIS of waste by eliminating a specific holding period prior to disposal. Please review the RIS 2004-17, and the revised condition carefully to ensure that you understand its requirements.

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).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for

L. Fedele
E. R. Squibb & Sons

2

review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

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. 108

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

L. Fedele
E. R. Squibb & Sons

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DATE	1/26/05						

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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 style="text-align: center;">Licensee</p> <p>1. E. R. Squibb & Sons, Inc.</p> <p>2. 311 Pennington-Rocky Hill Road Mail Stop HW8T-1.12 Pennington, New Jersey 08534-2130</p>	<p>In accordance with the letter dated November 22, 2004,</p> <p>3. License number 29-00139-02 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date September 30, 2008</p> <hr/> <p>5. Docket No. 030-05222 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material with atomic numbers 1 through 83, except Strontium 90</p> <p>B. Hydrogen 3</p> <p>C. Carbon 14</p> <p>D. Strontium 90</p> <p>E. Technetium 99m</p> <p>F. Any byproduct material with atomic numbers 84 through 103</p> <p>G. Nickel 63</p> <p>H. Any byproduct material with atomic numbers 1 through 83, except Strontium 90</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. Foil or plated sources registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State.</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 per radionuclide and 2 curies total</p> <p>B. 150 curies</p> <p>C. 20 curies</p> <p>D. 2 millicuries</p> <p>E. 750 millicuries</p> <p>F. 1 millicurie</p> <p>G. 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> <p>H. 200 millicuries per radionuclide and 6 curies total</p>
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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-00139-02

Docket or Reference Number
030-05222

Amendment No. 108

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
I. Hydrogen 3	I. Any	I. 250 curies
J. Carbon 14	J. Any	J. 25 curies
K. Phosphorus 33	K. Any	K. 1 curie
L. Sulfur 35	L. Any	L. 10 curies
M. Iodine 125	M. Any	M. 500 millicuries
N. Any byproduct material with atomic numbers 1 through 83, except, Strontium 90	N. Any	N. 200 millicuries per radionuclide and 6 curies total
O. Hydrogen 3	O. Any	O. 1 curie
P. Carbon 14	P. Any	P. 1 curie
Q. Sulfur 35	Q. Any	Q. 300 millicuries
R. Calcium 45	R. Any	R. 300 millicuries
S. Any byproduct material with atomic numbers 1 through 83, except Strontium 90	S. Any	S. 10 millicuries per radionuclide and 1 curie total
T. Hydrogen 3	T. Any	T. 100 millicuries
U. Carbon 14	U. Any	U. 100 millicuries
V. Sulfur 35	V. Any	V. 300 millicuries
W. Phosphorous 32	W. Any	W. 100 millicuries
X. Phosphorous 33	X. Any	X. 200 millicuries
Y. Iodine 125	Y. Any	Y. 50 millicuries

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-00139-02

Docket or Reference Number
030-05222

Amendment No. 108

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|---|---|---|
| <p>6. Byproduct, source, and/or special nuclear material</p> <p>Z. Cesium 137</p> | <p>7. Chemical and/or physical form</p> <p>Z. Sealed Sources
(J. L. Shepherd and
Associates Model 6810)</p> | <p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>Z. No single source to exceed the maximum activity per source or maximum activity per device specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State</p> |
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9. Authorized use:

- A. through F., and H. through Y. Research and development as defined in 10 CFR 30.4; animal studies; and calibration and checking of the licensee's instruments.
- B. and C. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72.
- G. 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.
- Z. For irradiation of materials in self-shielded irradiator devices that have been registered either with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State and which 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.

CONDITIONS

10. A. Licensed material in Items 6.A. through 6.G. may only be used at the licensee's facilities located at One Squibb Drive, New Brunswick, New Jersey.
- B. Licensed material in Items 6.G., 6.H. through 6.M., and 6.Z. 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.G. and 6.N. through 6.R. may only be used at the licensee's facilities located at 311 Pennington-Rocky Hill Road, Pennington, New Jersey.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-00139-02Docket or Reference Number
030-05222

Amendment No. 108

- D. Licensed material in Items 6.G. and 6.S. through 6.Y. 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.
- 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.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-00139-02Docket or Reference Number
030-05222

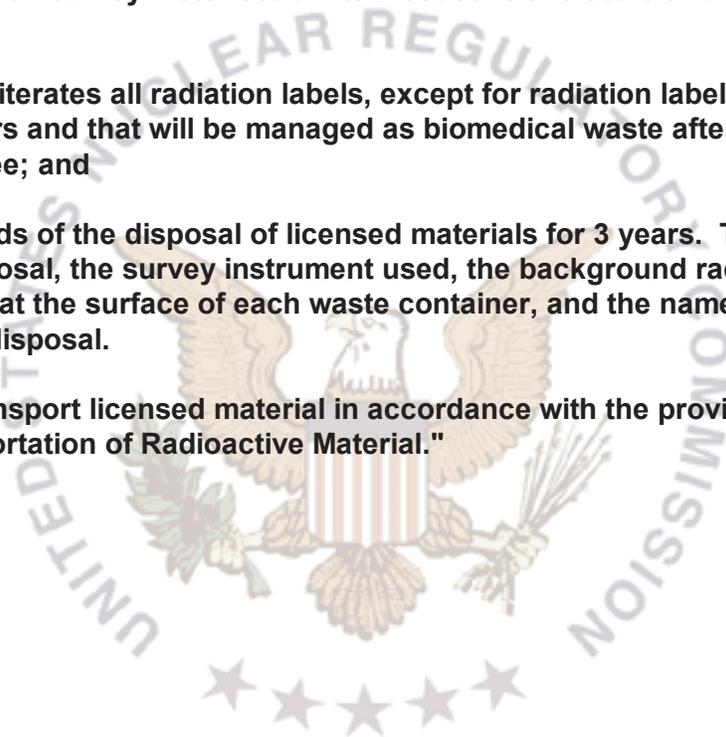
Amendment No. 108

- 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. 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.**
- 19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.**
- 20. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed 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.**

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
29-00139-02Docket or Reference Number
030-05222

Amendment No. 108

22. 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.
23. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."



**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-00139-02

Docket or Reference Number
030-05222

Amendment No. 108

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 June 20, 1994
- B. Application dated February 18, 1997
- C. Letter dated August 19, 1998
- D. Letter dated October 2, 2001 [ML012840012]
- E. Letter dated October 15, 2001 [ML012920254]
- F. Letter dated February 6, 2002 [ML020390283]
- G. Letter dated April 24, 2002 [ML021220488]
- H. Letter dated March 19, 2003 [ML030900805]
- I. Letter dated November 22, 2004 [ML043380281]



For the U.S. Nuclear Regulatory Commission

Original signed by Elizabeth Ullrich

Date **January 26, 2005**
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By _____
Elizabeth Ullrich
Commercial and R&D Branch
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King of Prussia, Pennsylvania 19406