

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 10, 2003

Docket No. 03005222 License No. 29-00139-02

Control No. 132495

John Mamone
Vice President, Operations Support
E. R. Squibb & Sons, Inc.
Mailstop HW8T-1.12
311 Pennington-Rocky Hill Road
Pennington, NJ 08534-2130

SUBJECT: E. R. SQUIBB & SONS, INC., ISSUANCE OF LICENSE AMENDMENT,

CONTROL NO. 132495

Dear Mr. Mamone:

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

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/reading-rm.html.

Thank you for your cooperation.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich Senior Health Physicist Nuclear Materials Safety Branch 2 Division of Nuclear Materials Safety

Enclosure:

Amendment No. 104

cc:

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

J. Mamone	
E. R. Squibb & Sons, Inc.	

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NAME	EUllrich /BU/					
DATE	1/10/03					

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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 ma source, and s deliver or tran shall be deer	ade by the licensee, a license is her special nuclear material designated asfer such material to persons autho ned to contain the conditions spec	eby is belov rized ified i	ssued authorizing w; to use such m to receive it in aco n Section 183 of	the licensee to rece aterial for the purpos cordance with the reg the Atomic Energy A	ive, a se(s) a julation	ance on statements and representations cquire, possess, and transfer byproduct, and at the place(s) designated below; to ons of the applicable Part(s). This license 1954, as amended, and is subject to all in effect and to any conditions specified
	Licensee			In accordance v	vith t	the letter dated
				December 16, 2	2002	,
1. E. R. Sc	quibb & Sons, Inc.			3. License numbe	r 29-	00139-02 is amended in
		. 1	EAR R	its entirety to re	ad a	s follows:
2. 311 Per	nnington-Rocky Hill Road	5		4. Expiration date	Sep	tember 30, 2008
Mail Sto	p HW8T-1.12			5. Docket No. 030	0-05	222
Penning	ton, New Jersey 08534-2130)		Reference No.	, 7	2
	uct, source, and/or special r material	7.	Chemical and/o	r physical form	8.	Maximum amount that licensee may possess at any one time under this license
atomi	yproduct material with c numbers 1 through 83, t Strontium 90	A.	Any	Tourse of the same	Α.	100 millicuries per radionuclide and 2 curies total
B. Hydro	gen 3	В.	Any	De rel	В.	150 curies
C. Carbo	on 14	C.	Any 🧪	44	C.	20 curies
D. Stront	tium 90	D.	Any	4	D.	2 millicuries
E. Techr	netium 99m	Ε.	Any	**	E.	750 millicuries
-	yproduct material with c numbers 84 through 103	F.	Any		F.	1 millicurie
G. Nicke	I 63	G.	Foil or plated registered eit U.S. Nuclear Commission 10 CFR 32.2 Agreement S	ther with the Regulatory under 10 or with an	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
H. Any b	yproduct material with	Н.	Any		Н.	200 millicuries per radionuclide

atomic numbers 1 through 83, except Strontium 90

and 6 curies total

NRC FORM 374A U.S. NUCLEAR REGULATORY COMMISSION PAGE of **PAGES** License Number 29-00139-02 Docket or Reference Number **MATERIALS LICENSE** 030-05222 **SUPPLEMENTARY SHEET** Amendment No. 104 Byproduct, source, and/or special 7. Chemical and/or physical form Maximum amount that licensee may nuclear material possess at any one time under this license Hydrogen 3 7 curies Any J. 5 curies J. Carbon 14 K. Phosphorus 33 K. 1 curie L. Sulfur 35 Any L. 10 curies M. lodine 125 M. Any M. 500 millicuries N. Nickel 63 N. Foil or plated sources N. No single source to exceed the registered either with the maximum activity specified in U.S. Nuclear Regulatory the certificate of registration Commission under issued by the U.S. Nuclear 10 CFR 32.210 or with an Regulatory Commission or an Agreement State Agreement State O. Any byproduct material with O. 200 millicuries per radionuclide O. Any atomic numbers 1 through 83, and 6 curies total except, Strontium 90 500 millicuries P. Hydrogen 3 P. Any Q. Carbon 14 Q. Any Q. 500 millicuries R. Sulfur 35 R. Any R. 300 millicuries S. Calcium 45 S. Any S. 300 millicuries T. Nickel 63 T. Foil or plated sources T. No single source to exceed the registered either with the maximum activity specified in U.S. Nuclear Regulatory the certificate of registration Commission under issued by the U.S. Nuclear 10 CFR 32.210 or with an Regulatory Commission or an Agreement State Agreement State

U. Any

U. 10 millicuries per radionuclide

and 1 curie total

U. Any byproduct material with

except Strontium 90

atomic numbers 1 through 83,

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		Amendment No. 10)4				

Byproduct, source, and/or special 7. Chemical and/or physical form Maximum amount that licensee may possess at any one time under this nuclear material license V. Hydrogen 3 V. 100 millicuries V. Any W. Carbon 14 W. Any W. 100 millicuries X. Any X. Sulfur 35 X. 300 millicuries 100 millicuries Y. Phosphorous 32 Z. Phosphorous 33 Z. Any Z. 200 millicuries AA. Iodine 125 AA. 50 millicuries AA. Any BB. Nickel 63 BB. Foil or plated sources BB. No single source to exceed registered either with the the maximum activity U.S. Nuclear Regulatory specified in the certificate of Commission under registration issued by the 10 CFR 32.210 or with an U.S. Nuclear Regulatory Commission or an Agreement State Agreement State CC. Sealed Sources (J.L. Cesium 137 No single source to exceed Shepherd and Associates the maximum activity per Model 6810) source or maximum activity per device specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission or an Agreement State

9. Authorized use:

- A., B., C., D., and F. Research and development as defined in 10 CFR 30.4; animal studies; and calibration and checking of the licensee's instruments.
- E. Research and development as defined in 10 CFR 30.4; animal studies.
- B. and C. Preparation and distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72.

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H. through M., O. through S., and U. through AA.

Research and development as defined in 10 CFR 30.4; animal studies; and calibration and checking of the licensee's instruments.

- G., N., T., and BB. 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.
- CC. 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.H. through 6.N. and 6.CC. 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.O. through 6.T. 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.U. through 6.BB. 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.

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- 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.
 - 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.

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- 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.
- 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. For each J. L. Shepherd and Associates, Mark I or Model 81-22, cesium-137 irradiator installed and used, the licensee shall:
 - A. Permit the use of the irradiator only when a calibrated and operable radiation survey meter or room monitor is available: and
 - B. Permit the irradiator door to be opened only after the operator has checked visual indicators to verify that the source has returned to its safe storage position; and
 - C. Have room monitors installed that will:
 - (i) Operate at all times when the irradiator is in use; and
 - (ii) Activate a visible and audible alarm when radiation exceeds 2 millirems per hour; and
 - (iii) Detect any radiation leaking from the irradiator door; and
 - (iv) Be visible to the irradiator user when the user is next to the irradiator; or
 - D. If a room monitor is not installed, have available a calibrated and operable survey meter which will be used to:
 - (i) Determine the radiation level at the irradiator door when the door is closed; and
 - (ii) Check for any increase in radiation levels each time the irradiator door is opened.

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- E. If abnormal radiation levels or any malfunctions of the irradiator are detected at any time, the licensee shall cease using the irradiator, restrict access to the area housing the irradiator, immediately notify the Radiation Safety Officer, and submit all reports required under 10 CFR Parts 20, 21 or 30.
- F. Not repair or authorize repairs of the irradiator except by the manufacturer or other persons specifically authorized by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- 22.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.
- 23. 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.
- 24. 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.
- 25. 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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Date	e	January 10, 3	2003		Or By	iginal signed by E	Elizabeth	Ullr	ich		
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