

MATERIALS LICENSE

Amendment No. 76

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, 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 and Sons, Inc.
2. P.O. Box 191
New Brunswick, New Jersey 08903

In accordance with letter dated
September 26, 1988,

3. License number 29-00139-02 is amended in its entirety to read as follows:

4. Expiration date March 31, 1989

5. Docket or
Reference No. 030-05222

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

- A. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90
- B. Iodine 131
- C. Molybdenum 99/
Technetium 99m
- D. Any byproduct material with Atomic Nos. 1-83 inclusive, except Strontium 90
- E. Hydrogen 3
- F. Carbon 14
- G. Sulfur 35
- H. Nickel 63

7. Chemical and/or physical
form

- A. Any
- B. Any
- C. Any
- D. Any
- E. Any
- F. Any
- G. Any
- H. Plated sources in detector cells

8. Maximum amount that licensee
may possess at any one time
under this license

- A. 5 curies of each radionuclide, with a total possession limit of 1000 curies
- B. 150 curies
- C. 2000 curies
- D. 200 millicuries of each radionuclide with a total possession limit of 5 curies
- E. 2 curies
- F. 4 curies
- G. 2 curies
- H. Not to exceed 15 millicuries per source
- I. 10 millicuries of each radionuclide, with a total possession limit of 1 curie
- J. Not to exceed limits specified for each radionuclide in Schedule B, 10 CFR 30.71

- I. Any byproduct with Atomic Nos. 1-83 inclusive, except Strontium 90
- J. Any byproduct material listed in Schedule B, 10 CFR 30.71

- I. Any
- J. Any radioimmunoassay kit

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REQ1 LTC30
29-00139-02 PDR

9. Authorized use

- A., B., and C. (1) Research and development as defined in Section 30.4(q) of 10 CFR 30.
(2) For possession use and processing incident to the manufacture of radiochemicals and radiopharmaceuticals.

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(9. Continued)

- (3) For storage prior to distribution of manufactured radiochemicals and radiopharmaceuticals.
- (4) For packaging and distribution of manufactured radiochemicals and radiopharmaceuticals to persons authorized to receive the licensed material pursuant to the terms and conditions of a specific license issued by the Nuclear Regulatory Commission or an Agreement State.

D. through I. Research and development as defined in Section 30.4(q) of 10 CFR 30.

J. For demonstration by sales personnel at customer's facilities.

CONDITIONS

- 10. A. Licensed material in Items 6.A., B., C. and H. shall only be used at licensee's facilities at Rt. 1, North Brunswick, New Jersey.
- B. Licensed material in Items 6.D., E., F., G. and H. shall only be used at licensee's facilities in Lawrenceville, New Jersey and 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey.
- C. Licensed material in Item 6.H. and I. shall only be used at licensee's facilities, Princeton House, 905 Herrontown Road, Princeton, New Jersey.
- D. Licensed material in Item 6.J. may be demonstrated at temporary job sites of the licensee anywhere in the United States where the Nuclear Regulatory Commission maintain jurisdiction for regulating the use of byproduct material.
- 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 Edward J. Truskowski.
- 12. A(1) Each sealed source or detector cell acquired from another person and containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for contamination and/or leakage before use. In the absence of a certificate from a transferor indicating that a test has been made within 6 months before the transfer, a sealed source received from another person shall not be put into use until tested.
- (2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.
- (3) Except for alpha sources, the periodic leak test required by this condition does not apply to sealed sources that are stored and not being used. The sources excepted from this test shall be tested for leakage before any use or transfer to another person unless they have been leak tested within 6 months before the date of use or transfer.

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29-00139-C2

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CONDITIONS

- B. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to use or transfer as a sealed source. If the inspection or test reveals any construction defects or 0.005 microcurie or greater of contamination, the source shall not be used or transferred as a sealed source until it has been repaired, decontaminated and retested.
- C. Each sealed source or detector cell containing licensed material, other than hydrogen 3, with a half-life greater than 30 days and in any form other than gas shall be tested for leakage and/or contamination at intervals not to exceed 6 months except that each source designed for the purpose of emitting alpha particles shall be tested at intervals not to exceed 3 months.
- D. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Commission. Records may be disposed of following Commission inspection.
- E. If the test required by Subsection A. or C. of this condition reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U. S. Nuclear Regulatory Commission, Region I, ATTN: Chief, Nuclear Materials Safety Branch, 475 Allendale Road, King of Prussia, Pennsylvania 19406, describing the equipment involved, the test results, and the corrective action taken.
13. In lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as provided in Section 20.203(a)(1), of 10 CFR Part 20, the licensee is hereby authorized to label detector cells and cell baths, containing licensed material and used in gas chromatography devices, with conspicuously etched or stamped radiation caution symbols without a color requirement.
14. Detector cells containing titanium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 225 degrees Centigrade.
15. Detector cells containing scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents foil temperatures from exceeding 325 degrees Centigrade.

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(Continued)

CONDITIONS

16. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 2 years from the date of each inventory.
17. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material".
18. Experimental animals administered licensed materials or their products shall not be used for human consumption.
19. Licensed material shall not be used in or on human beings.
20. This license does not authorize the distribution of byproduct material for medical use under general license pursuant to Paragraph 35.31, 10 CFR 35.
21. This license does not authorize the commercial distribution of exempt quantities of licensed material pursuant to Section 30.18, 10 CFR 30, and Section 32.18, 10 CFR 32.
22. The licensee shall maintain, and execute the response measures of his Radiological Contingency Plan submitted to the Commission on June 29, 1981, as revised on December 4, 1981, March 17, 1982, May 27, 1983, April 3, 1985, August 6, 1985, April 1, 1986, June 12, 1986 and June 15, 1987. The licensee shall also maintain implementing procedures for his Radiological Contingency Plan as necessary to implement the Plan. The licensee shall make no change in his Radiological Contingency Plan that would decrease the response effectiveness of the Plan without prior Commission approval as evidenced by license amendment. The licensee may make changes to his Radiological Contingency Plan without prior Commission approval if the changes do not decrease the response effectiveness of the Plan. The licensee shall maintain records of changes that are made to the Plan without prior approval for a period of two years from the date of the change and shall furnish the Chief, Material Licensing Branch, Division of Fuel Cycle and Material Safety, NMSS, U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, and the appropriate NRC Regional office specified in Appendix D of 10 CFR Part 20, a report containing a description of each change within six months after the change is made.
23. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:
 - A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

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CONDITIONS

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 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 29, 1981
- B. Letter dated December 4, 1981
- C. Letter dated March 17, 1982
- D. Letter dated June 22, 1982
- E. Letter dated December 15, 1982
- F. Application dated May 17, 1983
- G. Letter dated May 27, 1983
- H. Letter dated June 6, 1983
- I. Letter dated July 11, 1983
- J. Letter dated October 17, 1983
- K. Letter dated December 14, 1983
- L. Letter dated February 17, 1984
- M. Letter dated September 10, 1984
- N. Letter dated February 7, 1985
- O. Letter dated April 3, 1985
- P. Letter dated July 5, 1985
- Q. Two letters dated August 5, 1985
- R. Letter dated August 6, 1985
- S. Letter dated December 4, 1985
- T. Letter dated February 24, 1986
- U. Letter dated April 1, 1986
- V. Letter dated June 12, 1986
- W. Letter dated July 29, 1986
- X. Letter dated December 1, 1986
- Y. Letter dated December 16, 1986
- Z. Two letters dated February 16, 1987
- AA. Letter dated June 15, 1987
- BB. Letter dated January 22, 1988
- CC. Letter dated September 26, 1988
- DD. Letter dated November 21, 1988
- EE. Letter dated December 27, 1988

For the U.S. Nuclear Regulatory Commission

Original Signed By:

By Francis M. Costello

Nuclear Materials Safety Branch
Region I

King of Prussia, Pennsylvania 19406

Date 13 JAN 1989

13 JAN 1989

License No. 29-00139-02
Docket No. 030-05222
Control No. 109938

E. R. Squibb and Sons, Incorporated
ATTN: Edward J. Truskowski
Radiation Safety Officer
Squibb Institute for Medical
Research
One Squibb Drive
P.O. Box 191
New Brunswick, New Jersey 08903-0191

Gentlemen:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5239, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

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ML 29-00139-02/LTR - 0001.0.0
01/05/89

We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:
Francis M. Costello
Francis M. Costello
Nuclear Materials Safety Section B
Division of Radiation Safety
and Safeguards

Enclosures:

1. Amendment No. 76
2. Requirements for Materials Licensees

PMC
DRSS:RI
Costello/tlm

1/11/89

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ML 29-00139-02/LTR - 0002.0.0
01/05/89

MS-16
K-9



**Squibb
Technical Operations**

December 27, 1988

Mr. Frank Costello
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pa. 19406

Re: License Amendment
License #29-00139-02
Control #109938

Dear Mr. Costello:

This letter is additional information to my November 21, 1988 amendment request for the above noted NRC license.

My status as Radiation Safety Officer and secretary on the Radiation Safety Committee requires that my resume be on file. It is attached.

The facility at 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey is a one story facility located in an industrial park. It is leased by Squibb to house our new oncology group. On the attached diagram of the facility please note that labs 6, 8 and 9 and a storage room near the shipping dock are the presently planned restricted areas. No generation of radioactive material waste of a biological category is presently planned.

If there are any questions please feel free to contact me.

E. Truskowski

E. Truskowski
Radiation Safety Officer,
E. R. Squibb & Sons

ET/df
Attachments

109938
12-30-88

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Edward J. Truskowski

(b)(6)

EXPERIENCE:

E.R. Squibb & Sons
New Brunswick, N.J.
June 1977 - present

Health Physics Supervisor: Evaluate and audit radiopharmaceutical manufacturing and research and development procedures for compliance with radiation safety practices in accordance with federal and state regulations. Supervise union Health Physics technicians. Prepare and update personal computer programs for: storage and analysis of individual's radiation exposure history; daily health physics surveys and assays; and updating radiation safety, waste management, ALARA, and radiological contingency plan procedures manuals. Set up and maintained GeLi detection and analysis system for product and environmental samples. Develop and implement training programs on radiation safety procedures and emergency drills. Participate in federal and state regulatory inspections. Prepare records and reports to satisfy our regulatory requirements and keep personal radiation doses and environmental effluents ALARA.

Rutgers University
New Brunswick, N.J.
Nov 1981 - Dec 1984

Radiation Science Instructor: teach operational Health Physics course for the Coordinating Council on Radiation Science. This course is offered at power reactors to upgrade employees to Health Physics technicians.

E.R. Squibb & Sons
New Brunswick, N.J.
Dec 1976 - June 1977

Analytical Chemist: Medotope Division - Analyze and prepare standards from NBS. Perform radiochemical purity and bio-efficacy tests on radiochemical products.

Rutgers University
New Brunswick, N.J.
Aug 1976 - Dec 1976

Health Physics Assistant: Assist university's radiation safety officer in: surveying x-ray machines in local hospitals for state regulations and updating university's computerized radioactive material inventory. Supervision of health physics safety procedures for radioactive iodine labeling of protein. Electron beam dose calculations from an 18Mev accelerator using Fricke dosimeter and TLD's. Supervision of undergraduate applied health physics laboratory.

Brookhaven Nat. Lab
Upton, N.Y.
June 1976 - Aug 1976

Health Physics Graduate Student Fellow:
Concentrated my work as an operational
Health Physicist at the high flux beam
reactor. Also participated in projects in
almost every department with health physics
concerns on the site.

ATI/Chem-Spray
5 Taft Rd.
Totowa, N.J.
1973 - June 1976

Supervisor of Cost and Inventory: Supervise
proper flow of paperwork for all billings
and inventory analysis. Compute all job
cost estimates for new business quotes.
Set up and maintain cost system for over
500 aerosol and cosmetic products. Analyze
differences between actual and standard
costs for divisional statement purposes.

1971-1973

Inventory Control Supervisor: Set up
perpetual inventory system dealing with
thousands of components having a large
turnover. Improved customer relations
concerning the handling of their
inventories.

Manhattan College
Physics Dept.
1970 - 1971

Laboratory Assistant: Assisted in
construction, set up and maintenance of
Physics Laboratory.

EDUCATION:

Rutgers University
New Brunswick, N.J.

(b)(6)

Master of Science: Radiation Science:
Radiation: Physics, Chemistry, Biology,
Instrumentation and Dosimetry; Micrometeor-
ology; Special Topics in Health Physics;
Environmental Impact Statement and
Analysis; Air Sampling and Analysis;
Nuclear Energy Technology.

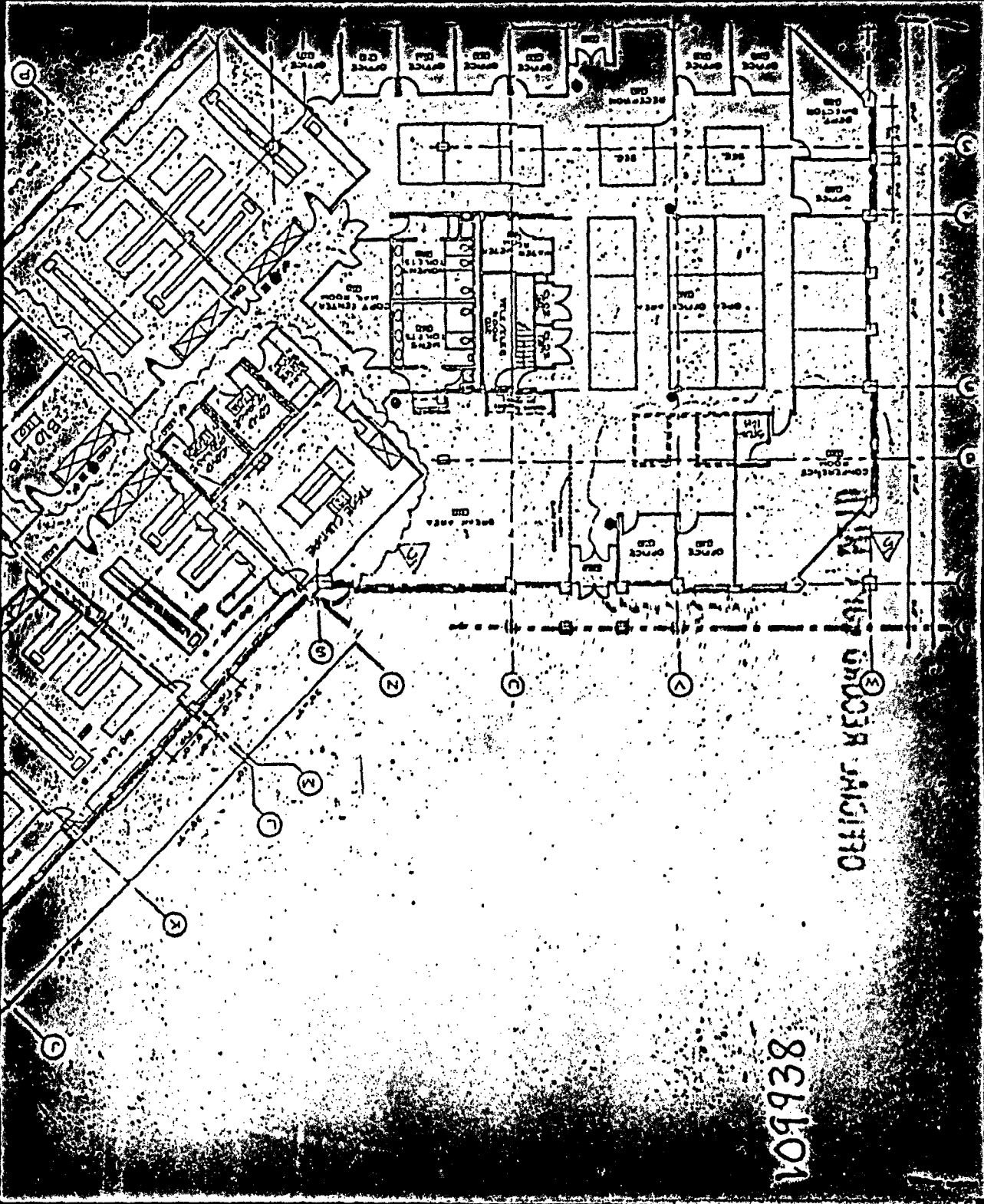
Manhattan College
Bronx, N.Y.

(b)(6)

Bachelor of Science Degree: Physics
including Modern Physics, Atomic and
Nuclear, Waves and Vibrations, Mechanics,
Electromagnetic Radiation, Quantum
Mechanics, and Solid State. Mathematics
including Honors Calculus, Linear Algebra,
and Complex Variables. Chemistry: Organic
and Organic Laboratory.

REFERENCES:

Furnished upon request.



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LICENSE NO. 29-00139-02
DOCKET NO. 30-05222
CONTROL NO. 109938

NAME E. R. SQUIBB & SONS, INC.
ATTN: EDWARD J. TRUSKOWSKI, RSO
ADDRESS ONE SQUIBB DRIVE P.O. BOX 191
NEW BRUNSWICK, NJ 08703-0191

GENTLEMAN,

THIS IS TO CONFIRM OUR TELEPHONE CONVERSATION ON 12/21/88
WITH you IN WHICH WE DISCUSSED THE INFORMATION
WE NEED TO CONTINUE REVIEW OF YOUR APPLICATION DATED 11/21/88.

THE ITEMS SPECIFIED BELOW ARE THOSE WE DISCUSSED.

1. *Submit resume which was not attached to application*
- 2.
- 3.

IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS
FROM THE DATE OF THIS LETTER, WE SHALL ASSUME THAT YOU DO NOT
WISH TO PURSUE YOUR APPLICATION.

SINCERELY,

Frank Corbett
NUCLEAR MATERIALS SAFETY SECTION B
NUCLEAR MATERIALS SAFETY AND SAFEGUARDS BRANCH

CONCURRENCES: -----

030-05222



Squibb Technical Operations

November 21, 1988

Dr. Josephine Piccone
U.S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, Pa. 19406

Re: License Amendment
License #29-00139-02

Log ME.6
Remitter _____
Check No. 288315
Amount \$120
Fee Category 3A
Type of Fee AMP
Date Check Rec'd. 12/12/57
Date Completed 12/12/57
By: S. Kimberly

Dear Dr. Piccone:

This is to request that E.R. Squibb & Son's Radioactive Material License Number 29-00139-02 be amended to include:

1. The addition of the Forrestal Greens facility located at 675 College Road East, Princeton Forrestal Center, Plainsboro, New Jersey.

The laboratory will process radioactive material for research (as defined by 10CFR30.4g) in Oncology. Specific isotope possession limits will be:

<u>Isotope</u>	<u>Form</u>	<u>Possession Limit</u>
P-32	Any	100 mCi.
S-35	Any	100 mCi.
C-14	Any	40 mCi.
I-125	Any	20 mCi.
H-3	Any	40 mCi.
Nickel	Plated sources in detector cells	Not to exceed 15 millicuries per source

All activities involving the use of radioactive materials at this site will be conducted in accordance with E.R. Squibb & Sons overall radiation safety program, under the control of the Radiation Safety Officer and the Radiation Safety Committee.

109938

NOV 30 1988

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Dr. Josephine Piccone

-2-

November 21, 1988

2. The name and street address for our New Brunswick facility has been changed to:

E.R. Squibb & Sons, Inc.
One Squibb Drive
P.O. Box 191
New Brunswick, N.J. 08903-0191

3. Mr. E. Truskowski is the Radiation Safety Officer replacing Mr. D. Balkunow and is also the secretary of the Radiation Safety Committee. His resume is attached.

Attached is a check for \$120.00 to cover the cost of processing this amendment.

Sincerely,

Edward J. Truskowski

Edward J. Truskowski
Radiation Safety Officer
E.R. Squibb & Sons

EJT:cr

Enclosure

cc: Dr. H. Abdou	Dr. M. Loberg
Mr. D. Balkunow	Mr. W. McGrath
Mr. H. Bartlett	Dr. E. Nickoloff
Dr. E. Eaton	Dr. P. Roets
Dr. W. Eckelman	Mr. G. Thompson
Mr. J. Gresh	Mr. E. Truskowski
Mr. H. Harrison	Dr. J. Zodda

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109938

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03211
STATUS CODE: 0
FEE CATEGORY: 3A
EXP. DATE: 19890331
FEE COMMENTS: -----
.....

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: E. R. SQUIBB & SONS, INC.
RECEIVED DATE: 881130
DOCKET NO: 3005222
CONTROL NO.: 109938
LICENSE NO.: 29-00139-02
ACTION TYPE: AMENDMENT

2. FEE ATTACHED
AMOUNT: \$120.00
CHECK NO.: 288315

3. COMMENTS

SIGNED
DATE

EMD
DEC 2, 1988

5. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED) ☒

1. FEE CATEGORY AND AMOUNT: 3A \$120

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
AMENDMENT _____
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED
DATE

J. Kimbrey
12/12/88

PA 12/2