

E. R. Squibb & Sons, Inc.

SQUIBB

Georges Road
New Brunswick, N.J. 08903
201-545-1300

December 1, 1986

Log	Dec 20
Remitter	
Check No.	837448
Amount	6.50
Fee	3A
Type of	Amendment
Date Check Made	12/31/86
Date Completed	12/31/86
By	J. H. H. H. H.

Ms. J. Johansen
U. S. Nuclear Regulatory Commission
Region I
531 Park Avenue
King of Prussia, PA 19406

DEC 31 1986

Reference License # 29-00139-02

Dear Ms. Johansen:

This is a request that E. R. Squibb & Son's radioactive material license number 29-000139-02 be amended to reflect:

- A. Changes in Squibb's Radiation Safety Committee.
- B. The inclusion of site limitations and additional byproduct materials.
- C. The addition of byproduct material and changes in site limitations for the Clinical Support Laboratory located at the Princeton House, 905 Herrontown Rd., Princeton, New Jersey.

A. Radiation Safety Committee Changes

1. Mr. J. Reinhardt replaces Mr. J. Zelenski as a Radiation Safety Committee member.
2. Mr. B. Sueskind has become a member of the committee.
3. Ms. E. Nickoloff, PhD, has become a member of the committee.
4. Dr. G. Gennaro has become a member of the committee.

Enclosed for your records are the biographical profiles of the new committee members along with an updated listing of the committee.

B. Byproduct Material/Possession Limits

Please amend Squibb's license to include the following Byproduct materials.

8706050150 870225
REG 1 11630
29-00139-02

Information in this record was deleted in
accordance with the Freedom of Information Act
DATE 10/15/86 BY 1016/LS

"OFFICIAL RECORD COPY"

E/14
106573

DEC 22 1986

Byproduct Material

Chemical or
Physical FormPossession
Limits

Yttrium 90	Any	100 mCi
Yttrium 88	Any	10 mCi
Yttrium 91	Any	10 mCi
Cerium 144	Any	10 mCi
Samarium 153	Any	100 mCi
Rhenium 188	Any	10 mCi

The above materials will be used exclusively in non-human research and development studies.

C. Princeton House - Byproduct Material/Possession Limits

Please amend Squibb's license to reflect an increase of possession limits and the addition of the following byproduct materials for use at the Clinical Support laboratory located at the Princeton House.

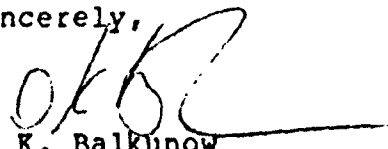
Byproduct Material	Form	Present Amount	Requested Increase
Hydrogen 3	Any	2 mCi	10 mCi
Carbon 14	Any	2 mCi	10 mCi
Iodine 125	Any	2 mCi	10 mCi
Iron 59	Any	2 mCi	10 mCi
Chromium 51	Any	2 mCi	10 mCi

Please include the following Byproduct material for non-human use in the Clinical Support laboratories located at the Princeton House.

Byproduct Material	Form	Requested Amount
Phosphorus 32	Any	10 mCi
Rubidium 86	Any	10 mCi
Nickel 63	Plated Source contained in Electron Capture Detector	Not to exceed 15 mCi

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

Sincerely,


D. K. Balkunow
Radiation Safety Officer
E. R. Squibb & Sons, Inc.

DKB/ld1

ADDENDUM #1

Radiation Safety Committee Membership

1. Mr. J. P. Gresh, Committee Chairman, Manager, Training Department.
2. Mr. R. Healy, Director, Human Resources.
3. Mr. G. Thompson, Manager, Radiodiagnostic Production.
4. Dr. E. Eaton, Assistant Associate Corporate Medical Director.
5. Dr. M. Loberg, Vice-President and General Manager; Squibb Diagnostics.
6. Dr. P. Roets, Manager, Personnel, Industrial Hygiene and Safety.
7. Mr. H. Bartlett, Manager, Environmental Control.
8. Mr. D. K. Balkunow, Health Physics Department Head, and Radiation Safety Officer.
9. Dr. G. Gennaro, Section Head, Radioactive Products.
10. Dr. E. Nickoloff, Director, Scientific Information Resources.
11. Mr. J. Reinhardt, Director Radiodiagnostics Operations and Productivity.
12. Mr. B. Sueskind, Senior Attorney.

CURRICULUM VITAE

GERALD P. GENNARO, Ph.D.

Home Address:

(b)(6)

Office Address: The Squibb Institute for Medical Research
P.O. Box 191
New Brunswick, NJ 08903
(201) 519-3181

Date of Birth:

(b)(6)

Personal:

(b)(6)

Education:

Rutgers University, New Brunswick, NJ
B.S., Chemistry, (b)(6)
State University of New York, Buffalo, NY
Ph.D., Chemistry, (b)(6)

EXPERIENCE

- E.R. Squibb & Sons, New Brunswick, NJ
Section Head, 1984-Date
Senior Research Associate, 1982-1984
Research Associate, 1980-1982

Project development responsibility for 82-Sr/82-Rb radionuclide generator and lyophilized diagnostic agents. Responsible for manufacture and supply of clinical radiopharmaceuticals. Generated proposals for new products and product improvements. Composed testing standards and manufacturing documents. Radioanalytical assay development. Computation of absorbed radiation doses and shielding requirements for products and processes. Radiochemical purity by paper chromatography and radionuclidic purity by gamma spectrometry. Mo-99/Tc-99m generator research. Completed workshops in Time Management; Performance Planning and Appraisal; and Finance and Accounting. Appointed to Division Task Force on Cost Containment and two product-related Task Forces.

- Diagnostic Isotopes, Inc., Bloomfield, NJ
Director of Radiopharmaceutical Development, 1977-1979

Scientific Advisor to Regulatory Affairs, Quality Control, and Manufacturing. Process and analytical development for radiopharmaceuticals (e.g. Indium oxine [111-In] and Selenomethionine [75-Se]).

- Memorial Sloan-Kettering Institute, New York, NY
Research Scientist, 1975

Attempted radiofluorination (18-F) of estradiol as in-vivo radiotracer.

- Ramapo College of New Jersey, Mahwah, NJ
Assistant Professor of Chemistry, 1972-1977

Developed courses in Chemistry for Liberal Arts Majors; General Chemistry; Physical Chemistry; and Application of Radiation and Radioisotopes in Diverse Disciplines. Served as Program Coordinator for Chemistry; Chairman of Faculty Assembly and Personnel Committee for School of Theoretical and Applied Science. Secured NRC license for institution and served as Radiation Safety Officer. Granted Tenure in 1975.

- Texas A&M University, College Station, TX
Research Associate, 1971-1972

Postdoctoral research and laboratory management. Responsible for implementing program in hot atom chemistry of phosphorus and silicon. Cyclotron production of radioisotopes. Extensive use of vacuum techniques and radio-gas chromatography.

- State University of New York, Buffalo, NY
Research Assistant, 1967-70
Teaching Assistant, 1965-67

Reactor production of radioisotopes. Radioanalytical techniques.
Radio-gas chromatography.

PROFESSIONAL AFFILIATIONS

American Chemical Society, Division of Nuclear Chemistry and Technology
Society of Nuclear Medicine, Radiopharmaceutical Science Council
Journal of Nuclear Medicine, Manuscript Reviewer

BIBLIOGRAPHY

GENNARO GP: Hot Atom Chemistry of Organic Halides in Solution, Ph.D. Thesis, State University of New York at Buffalo, 1970;
Diss. Abstr. Int., 31, 5247B (1971).

GENNARO GP and COLLINS KE: Solution Phase Cerenkov Counting of 80g-Br and 80m-Br in the Presence of 82-Br., J. Radioanal. Chem., 5, 387-389 (1970).

GENNARO GP and COLLINS KE: Geminate Retention from Nuclear Isomeric Transition and Radiative Thermal Neutron Capture in Carbon Tetrabromide-Ethanol Solutions, J. Phys. Chem., 74, 3094-3101 (1970).

DANIEL SH, GENNARO GP, RANCK KM, and TANG YN: Recoil Tritium Reactions with Hexamethyldisilane in the Gas Phase, J. Phys. Chem., 76, 1249-1254 (1972).

COLLINS KE, COLLINS CH, KAPAUAN PA, NAVARRO QO, KAPAUAN AF, and GENNARO GP: The Half-life of Bromine 80g, J. Inorg. Nucl. Chem., 34, 2971-2973 (1972).

TANG YN, GENNARO GP, and SU YY: Direct Evidence for the Reaction of Monomeric Silicon Difluoride with 1,3-Butadiene, J. Amer. Chem. Soc., 94, 4355-4357 (1972).

GENNARO GP and TANG YN: Gas Phase Recoil Phosphorus Reactions I: Complete and Partial Retention of Bonds in PF_5 , J. Inorg. Nucl. Chem., 35, 3087-3094 (1973).

GENNARO GP and TANG YN: Gas Phase Recoil Phosphorus Reactions II: A Detailed Study of Pressure and Scavenger Effects, J. Inorg. Nucl. Chem., 36, 259-262 (1974).

GENNARO GP, SU YY, ZECK OF, DANIEL SH, and TANG YN: The Addition of Triplet and Singlet Silylene to 1,3-Butadiene, J. Chem. Soc., Chem. Commun., 637-638 (1973).

ZECK OF, GENNARO GP, and TANG YN: Relative Efficiencies of Hydrogen Abstraction by Recoil Phosphorus Atoms, J. Chem. Soc., Chem. Commun., 52-53 (1974).

ZECK OF, SU YY, GENNARO GP, and TANG YN: The Ground Electronic State of Silylene, J. Amer. Chem. Soc., 96, 5967-5973 (1974).

ZECK OF, GENNARO GP, and TANG YN: Gas Phase Recoil Phosphorus Reactions III: Systematic Study of Hydrogen Abstraction Reactions, J. Amer. Chem. Soc., 97, 4498-4503 (1975).

ZECK OF, SU YY, GENNARO GP, and TANG YN: Effect of Additives on the Reaction of Monomeric Silicon Difluoride with 1,3-Butadiene, J. Amer. Chem. Soc., 98, 3474-3477 (1976).

ZECK OF, FERKIERI RA, COPP CA, GENNARO GP and TANG YN: Gas Phase Recoil Phosphorus Reactions IV: Effect of Moderators on the Abstraction Reactions, J. Inorg. Nucl. Chem., 41, 785-789 (1979).

REEVES RJ, CARROLL RT, and GENNARO GP: Titration of Phytic Acid, Talanta, 26, 1033-1034 (1979).

TOSCH KW, HORNICK JS, and GENNARO GP: Radiochromatography of Indium (^{111}In) Oxine, J. Radioanal. Chem., 53, 345-349 (1979).

NEIRINCKX RD, KRONAUGE JF, GENNARO GP, and LOBERG MD: Evaluation of Inorganic Adsorbents for the Rubidium-82 Generator: I. Hydrous SnO_2 , J. Nucl. Med., 23, 245-249 (1982).

GENNARO GP, WEDEKING P, HANEY TA, NEIRINCKX RD, and LOBERG MD: An Evaluation of Analytical Techniques Used in the Development of Radionuclide Generators, J. Labelled Compounds Radiopharm., 19, 1533-1534 (1982).

NEIRINCKX RD, COHAVI S, GENNARO GP, LOBERG MD, KRONAUGE JF, GOLDSMITH SL, and O'BRIEN HA: Application of a Commercial Sr-82/Rb-82 Generator for Heart and Kidney Imaging, Nucl. Med. Biol. Adv., Proc. World Cong. 3rd, 1, 613-616, 1982 (Pub. 1983), Pergamon: Oxford, U.K.

GENNARO GP, NEIRINCKX RD, BERGNER B, et. al.: A Radionuclide Generator and Infusion System for the Delivery of Pharmaceutical Quality Rb-82, in "Radionuclide Generators: New Systems for Nuclear Medicine Applications," American Chemical Society, Washington, DC, 1984.

BERGNER BC, LOBERG MD, and GENNARO GP: Rubidium-82 Infusion System, in "Single Photon Ultrashort-lived Radionuclides," United States Department of Energy, CONF-830504, Washington, DC, 1985.

GENNARO GP, BERGNER BC, HANEY PS, et. al.: Radioanalysis of 82-Rb Generator Eluates, Appl. Radiat. Isotopes, in press.

DHAWAN V and GENNARO GP: An Alternative Approach to On-Line Monitoring of Elution Profiles of Rb-82 for Radioassay/Radiation Dosimetry, J. Nucl. Med., 27, 1038 (1986).

GENNARO GP and HANEY PS: Strontium-82/Rubidium-82 Generator, US Patent 4,597,951, July 1, 1986.

HANEY PS and GENNARO GP: Hydroxylapatite-based 82-Sr/82-Rb Generator, J. Labelled Compounds Radiopharm., in press.

ABSTRACTS AND PRESENTATIONS

American Chemical Society

Boston, 1972 (2)
New York, 1972 (2)
Dallas, 1973
Los Angeles, 1974
Houston, 1974 (Southwest Regional)
Chicago, 1975
Seattle, 1983

Chemical Institute of Canada
Toronto, 1967

International Hot Atom Chemistry Symposia

Cambridge, England, 1969
Julich, West Germany, 1973 (2)
Spa, Belgium, 1975

REFERENCES

- Dr. Kenneth E. Collins, Instituto de Quimica, Universidade Estadual de Campinas, Campinas, S.P., BRASIL
- Dr. Y.-N. Tang, Department of Chemistry, Texas A&M University, College Station, TX 77843
- Mr. James J. Finn, Marine Biologicals, Inc., 1715 South Shore Rd., Seaville, NJ 08223
- Dr. Roy S. Tilbury, University of Texas System Cancer Center, M.D. Anderson Hospital, 6923 Bertner Dr., Houston, TX 77030
- Dr. Eileen Nickoloff, E.R. Squibb & Sons, Princeton, NJ 08540

CURRICULUM VITAE

EILEEN NICKOLOFF, Ph.D.

PROFESSIONAL EXPERIENCE:

9/85-Present Director, Scientific Information Resources
Squibb Institute for Medical Research
Princeton, N.J.

Responsible for R&D Computer Group (Scientific Information Systems) which handles all scientific computer functions for R&D. Named R&D Coordinator for new building to be built on Princeton site. Responsible for Science Information at Squibb, which includes all library & literature searching functions.

9/84-9/85 Administrative Director, Diagnostic R&D
Squibb Institute for Medical Research
New Brunswick, N.J.

Responsible for all budgetary, personnel and scientific administrative functions including computer networking for a staff of 65 scientists.

1/80-9/85 Director, Clinical Assay R&D
Squibb Institute for Medical Research
New Brunswick, N.J.

Brought 13 immunoassays to market, including all research, development, validation, troubleshooting, antibody production, clinical studies and product coordination. Developed research assays for in-house use, including drugs, prostaglandins, bradykinin and complement factors.

1974-1980

Director, In-Vitro Laboratory

Director, Radiopharmacy

The Johns Hopkins Hospital
Baltimore, MD

Increased the number of in-vitro tests performed from 200 to 2500/month in four years. Supervised preparation and quality control testing for all clinical and research imaging agents.

1971-1974

Clinical Chemist

Harrisburg Hospital
Harrisburg, PA

Directed all clinical chemistry, dialysis, toxicology and urinalysis functions.

1970-1971

Supervisor, Core Laboratory

Thorndike Laboratory, Harvard Medical Unit
Boston City Hospital, Boston, MA

Directed Core Laboratory, setting up research assays. Validated assays for use in measuring blood changes during transcendental meditation.

BOARD CERTIFICATION:

American Board of Clinical Chemistry, 1976

**PROFESSIONAL
AFFILIATIONS:**

American Association for Clinical Chemistry

President, New Jersey Chapter, 1983-4

Clinical Ligand Assay Society

President, National, 1979-80

General Chairman, National Meeting, 1979, 1982

Society of Nuclear Medicine

Co-Vice Chairman RIA, 1979 National Meeting

EDUCATION:

St. Joseph's College, Brooklyn, N.Y.

B.A., Chemistry, (b)(6)

University of New Hampshire, Durham, N.H.

Ph.D., Organic Chemistry, (b)(6)

PUBLICATIONS:

10 Book Chapters

12 Journal articles

30 published abstracts



SQUIBB
Corporation

TO D.K. Balkuncw

DATE November 6, 1986

FROM B.R. Sueskind

COPY TO

SUBJECT BIOGRAPHIC PROFILE
RADIATION SAFETY COMMITTEE

In response to your memo dated October 31, 1986, I am providing the requested biographic profile.

1. Company Employment History:

Special Consultant: May, 1985 - December, 1985.

Senior Attorney: January, 1986 to date.

Responsibilities include providing legal representation and advice on legal and corporate matters, including environmental, health and safety matters.

2. Education:

BA, Queens College, (b)(6)

JD, New York University, (b)(6)

3. Special Education (if necessary):

Not necessary.

4. Personal:

a. Name: Burton R. Sueskind

b. Address:

(Office) Squibb Corporation
P.O. Box 4000
Princeton, NJ 08543-4000

(Home)

(b)(6)

Please let me know if you need anything further.

B.R. Sueskind
B.R. SUESKIND

BIOGRAPHICAL SUMMARY

* John P. Reinhardt
* Director, Operations and Productivity
Squibb Diagnostics

Education

University of Scranton, BS Biology/Chemistry (b)(6)
University of Tennessee, Graduate Studies, Pharmacology (b)(6)

Professional Experience

Analytical Chemist, Quality Control, E. R. Squibb & Sons	Jun-Oct 1957
Sales Representative, E. R. Squibb & Sons	1958-1969
* Technical Associate, Nuclear Medicine, E. R. Squibb & Sons	1969-1973
* Training Associate, Nuclear Medicine, E. R. Squibb & Sons	1973-1975
Product Manager, X-Ray Contrast Media, E. R. Squibb & Sons	1975-1979
* Director, Training, E. R. Squibb & Sons	1979-1981
* Product Manager, Nuclear Medicine, Squibb Diagnostics	1981-1983
* Marketing Services Manager, Squibb Diagnostics	1983-1986
* Director, Operations and Productivity, Squibb Diagnostics	1986-Present

Professional Societies

American Chemical Society 1969-1985
Society of Nuclear Medicine 1969-1986
Society of Nuclear Medicine (Technologist Section)

* During these periods, direct involvement with Health Physics training for sales staff and/or customers.

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

03211

3/89

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: E.R. Squabb and Son, Inc.

Application Dated: 12/1/86

Control No.: 106573

License No.: 21-CC-139-00

2. FEE ATTACHED

Amount: \$ 120.00

Check No.: 837448

3. COMMENTS

Signed B. Glenn Miller

Date 12/23/86

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3A ^{\$} 120

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed J. Kimbrey

Date 12/31/86

Note To: License Fee Management Section, ADM

From: Region 1

Subject: VOIDED APPLICATION

Control Number 106648

Applicant F. R. Squibb & Sons Inc

Date Voided 2/25/87

Reason for Void:

A Control No. 106648 done with control No. 106573

*after separate
review.*

Brenda P. Litchick 2/25/87
Signature Date

Attachment:
Official Record Copy
of Voided Action

OK LFM
w. reference

ML