Bristol-Myers Squibb Company
Worldwide Medicines Group

One Squibb Drive P.O. Box 191 New Brunswick, New Jersey 08903-0191

732-519-2000

030-05222

July 18, 2001

Ms. Pamela Henderson
US NRC Region I
475 Allendale Road
King of Prussia, PA 19406

RE: AMENDMENT TO RADIOACTIVE MATERIAL LICENSE #29-00139-02

Dear Ms. Henderson:

E.R. Squibb & Sons, a wholly owned subsidiary of Bristol-Myers Squibb Company, wishes to amend its radioactive license #29-00139-02 to remove processing, manufacture, and commercial distribution of radiopharmaceuticals from its licensed activities. We also wish to update the license limits to reflect current operations. Specifically, the following changes are requested:

- Change license condition 8.A from "5 curies per radionuclide and 1,000 curies total" to "100 millicuries per radionuclide and 2 curies total". The authorized use under condition 9.A should be changed to "Research and development as defined in 10 CFR 30.4 including animal studies; calibration of instruments" only.
- Change ^{131}I activity limits under license condition 8.B from 150 curies to 2 Curies. The authorized use under condition 9.B should be changed to "Storage for decay; research and development as defined in 10 CFR 30.4 including animal studies" only.
- Modify the authorized use for ^{3}H and ^{14}C under license conditions 9.C and 9.D to add "the manufacture and distribution of drugs containing byproduct material, pursuant to 10 CFR 32.72, to authorized recipients for human use research" at the New Brunswick facility.

    - *The E.R. Squibb facility in New Brunswick, New Jersey is registered with the federal Food and Drug Agency as a drug manufacturer. The registration number is 2211101; a copy of the registration is attached.*

- Delete 10 curies of ^{35}S in license condition 6.E for use at the New Brunswick facility.
- Delete 50 curies of $^{99}Mo/^{99m}Tc$ in license condition 6.N for use at the Lawrenceville facility.
- Delete 500 millicuries of ^{131}I in license condition 6.P for use at the Lawrenceville facility.
- Delete 200 millicuries of ^{99}Tc in license condition 6.Q for use at the Lawrenceville facility.
- Add 750 millicuries of ^{99m}Tc in any chemical form for use at the New Brunswick facility for "Research and development as defined in 10 CFR 30.4 including animal studies".
- Delete license condition 12 requiring a Radiological Contingency Plan (RCP).

    - *The RCP was required due to our manufacturing activities, specifically, the authorized use of 150 curies of ^{131}I. Current procedures developed to support the RCP will be reviewed and modified to reflect remaining licensed activities and ensure any incidents involving licensed materials are fully addressed.*

As stated in Michael Vala's letter dated July 2, 2001, it is our intention to decommission the facilities used for radiodiagnostic manufacturing after a decay period of approximately three (3) months. To support that project, we are also submitting a decommissioning plan for your review. If you wish to discuss the plan or any of the above license amendments, please contact Michael Vala at (732) 519-2987.

Sincerely, .

Susan Voigt
Chair, Radiation Safety Committee
Sr. Director, WWMG EHS

Attachments (2)

SV:bl

cc: M. Vala

This is to acknowledge the receipt of your letter/application dated

7-18-01, and to inform you that the initial processing which includes an administrative review has been performed.

Amend

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 130090.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

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: 20080930
Fee Comments: _____
Decom Fin Assur Reqd: Y

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: E. R. SQUIBB & SONS, INC.
   Received Date: 20010730
   Docket No: 3005222
   Control No.: 130090
   License No.: 29-00139-02
   Action Type: Amendment

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Signed Donna Gruber
Date 8/3/2001

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License _____

3. OTHER _____
   _____

Signed _____
Date _____