



Bristol-Myers Squibb Company

Worldwide Medicines Group

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

732-519-2000

RECEIVED
REGION 1

2001 OCT -9 PM 2:14

October 2, 2001

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

RE: **MAIL CONTROL NO. 130090: AMENDMENT TO RADIOACTIVE MATERIAL LICENSE #29-00139-02**

Dear Ms. Henderson:

In response to your questions regarding our amendment request of July 18, 2001, we are providing the following additional information and clarifications:

- The New Brunswick facility is currently registered as a drug manufacturer with the federal Food & Drug Administration (FDA). The registration number is 2211101 and a copy of the registration was submitted with our amendment request of July 18, 2001.
- E.R. Squibb will only prepare and distribute radioactive drugs for which the FDA has accepted an Investigational New Drug application. These drugs will contain no more than 500 microcuries of C^{14} or H^3 per dosage and will be manufactured, prepared, and transferred for non-commercial medical research (metabolism studies).
- The drugs will be labeled in accordance with 10CFR32.72(a)(4) and instrumentation utilized to assay the drugs will comply with 10CFR32.72(c)(1) and (2).
- With regard to our request for 750 millicuries of Tc^{99m} , we will not be obtaining a Mo^{99} generator to supply this material.
- With regard to waste storage, we currently have access to offsite disposal facilities and are not utilizing interim waste storage.

I trust this information is sufficient to complete the amendment of our license. If you require any additional information, please do not hesitate to contact me at (609) 818-4907. Your assistance with this issue has been greatly appreciated.

Sincerely,

Michael J. Vala

Michael J. Vala, CHP
Radiation Safety Officer/Manager, EHS

MJV:bl

cc: C. Woodard

130090
NMSS/RGNI MATERIALS-002



Bristol-Myers Squibb Company

Worldwide Medicines Group

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

732-519-2000

October 3, 2001

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

030-05222

**RE: INFORMATION NOTICE FOR RADIOACTIVE MATERIAL LICENSES #29-00139-02,
#29-00139-04MD, #29-00139-08**

Dear Ms. Henderson:

This letter is to inform you that the offices of the Radiation Safety Officer and all documents and records associated with the above referenced licenses have been relocated from the New Brunswick, NJ site to our Pennington, NJ site. Please change our mailing address to:

Michael J. Vala
Radiation Safety Officer
Bristol-Myers Squibb Company
311 Pennington-Rocky Hill Road
Mail Stop HW8T-1.12
Pennington, NJ 08534-2130

I can be reached at my new location at (609) 818-4907. If you require any further information, please do not hesitate to contact me.

Sincerely,

Michael J. Vala, CHP
Radiation Safety Officer/Manager, EHS

MJV:bl