030-05222

Bristol-Myers Squibb Company
Pharmaceutical Group Technical Operations
One Squibb Drive P.O. Box 191 New Brunswick, NJ 08903-0191
908 519-2000

June 20, 1994

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Bristol Myers Squibb
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By 7/11/94
By: Brenda Barnes

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Dr. Mohamed M. Shanbaky
Chief Research & Development Section
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: AMENDMENT REQUEST - LICENSE #29-00139-02

Dear Dr. Shanbaky:

To support Bristol-Myers Squibb's on-going drug development program, its NRC licensed subsidiary, E. R. Squibb & Sons, Inc., utilizes contract licensed medical facilities to administer our radiolabelled clinical drugs. As part of the contract with its collaborators, E. R. Squibb & Sons, Inc., NRC license #29-00139-02, will distribute its filed investigative new drugs labelled with radioactive materials to licensees duly authorized to administer to humans.

To ensure all activities are performed as authorized by the NRC and other regulatory agencies, an amendment to E. R. Squibb & Sons, Inc. (license #29-00139-02) is requested to:

- Accept from its licensed collaborator (The Medical Center at Princeton, NRC license #29-06750-01) product and product related materials. These materials are used in drug application, dosing and recovery clinical procedures. The investigational drugs are labelled with Carbon-14 (^{14}C) and/or Tritium (^{3}H). Dosing will include intravenous, oral and topical applications. The drug and drug related materials are defined as blood and blood related products, urine, saliva, feces, unused drug, dosing material, apparatuses used in dosing, applications, dose recovery and/or as specified in Investigation New Drug (IND) protocols and procedures.

- All radioactive material received by E. R. Squibb & Sons, Inc. is surveyed upon receipt and becomes part of our inventory. Radiolabelled materials used in manufacturing of clinical supplies are accounted for in batch production and filling procedures. During clinical administrations, accountability is maintained through IND records in accordance with 21 CFR, Chapter 1, Section 361.1. Records of such inventories shall be included in the site's overall inventory and will be made available for review by regulatory agencies.

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Prior to shipping any radiolabelled clinical drug to a collaborating facility, E. R. Squibb & Sons, Inc. shall verify that the facility is properly contracted and licensed to perform clinical administration. All product shipped by license #29-00139-02 shall be properly identified, labelled and packaged in accordance with DOT regulations. Any product or product related materials as described herein that is returned by a collaborator shall be used for analytical and recovery purposes prior to final disposal as radioactive.

The licensee shall collect, store, process and dispose of all waste from the products and product related materials in accordance with the existing approved waste procedures.

Included is a check for $460.00 to cover the cost of processing the amendment. If you have any questions or require additional information, please do not hesitate to contact me at 908-519-3721.

Sincerely,

Larry Gaines

Larry Gaines
Associate Manager
Health Physics Department

LG:bl

Enclosure

LGNRCAMEND.LTR