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UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

September 5, 2008

Docket No. 03005222 License No. 29-00139-02
Control No. 142708

Michael J. Vala, C.H.P.
Radiation Safety Officer
E.R. Squibb & Sons, Inc.
One Squibb Drive
P.O. Box 191
New Brunswick, NJ 08903-0191

SUBJECT: E.R. SQUIBB & SONS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO. 142708

Dear Mr. Vala:

This is in reference to your application dated August 12, 2008 requesting to renew Nuclear Regulatory Commission License No. 29-00139-02. In order to continue our review, we need the following additional information:

1. Currently you are license for 750 millicuries of technetium 99m at your New Brunswick facility. Your renewal application requested for this same amount of material but at your Lawrenceville facility instead of the New Brunswick facility. Please confirm our understanding of your application.

2. The amount of unsealed material with a half life of greater than 120 days has changed. This affects your Certification of Financial Assurance statement. Please submit a new Certification of Financial Assurance with the changed material amounts.

3. Please confirm that the latest update to the Decommissioning Funding Plan was March 2006. If you have updated the DFP since then please submit that plan.

4. Your license will be written in a format which requires modification of some possession limits and forms. In your response to this letter, please provide limits commensurate with your program and sealed source identification in the format shown below. For sealed sources and devices, please list all manufacturers and model numbers that you currently possess or may use in the future. When setting the limits for the materials below, please consider the maximum activity you will have on site at any one time including waste. For sealed sources in devices, you may wish to request a possession limit adequate to allow for the possession of a spare source during replacement of the source in the device.

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Materials	Form or Manufacturer/Model No.	Possession limit:
Nickel 63	Foils or Sealed Sources (Manufacturer ____, Model No. _____; Manufacturer ____, Model No. _____)	___ millicuries per source and _____mIllicuries total
Cs-137	Sealed Sources (Manufacturer ____, Model No. _____; Manufacturer ____, Model No. _____)	_____ Curies per source and _____ Curies total

5. Provide a description or an organizational chart which shows that the Radiation Safety Committee has a direct reporting path to senior management.

6. With regard to your Radiation Safety Committee:

   a. State the criteria used for selecting members

   b. Specify the minimum representation (quorum requirements) which will be required at each meeting and for voting. The minimum members considered acceptable for a quorum by NRC staff are: Chairperson, RSO, management representative, and committee member(s) representing the department/area from which radiation safety issues/request, to be discussed at a given meeting originated, and any other committee member whose field of expertise is necessary to assure all safety aspects of the issue/request have been addressed. Please note that it is generally not acceptable to have an alternate attend in place of the Chairperson or RSO.

7. Describe the criteria your Radiation Safety Committee (RSC) will use to approve authorized users for activities utilizing licensed material. These criteria should specify the minimum acceptable standards for training and experience of the users.

8. Provide diagrams of facilities designed or established for special uses (e.g., iodination facilities using greater than 10 millicuries per experiment, nuclear pharmacies, incinerators, compactors, large quantity/high activity processing facilities, instrument calibration facilities, waste handling or processing facilities, long-term waste storage facilities, irradiators, source fabrication facilities, nuclear medicine facilities, specifically designed therapy rooms, and brachytherapy source storage areas). Also, provide your authorization criteria for decay-in-storage facilities, iodination/tritiation laboratories, unsealed alpha laboratories, and animal facilities.

9. You have requested for distribution of radioactive drugs to authorized recipients in accordance with 10 CFR 32.72. You may apply for a separate license in accordance with NUREG-1556, Volume 12 for a medical distribution license. However, if you are manufacturing and distributing only Investigational New Drug (IND) protocol accepted by the FDA, you may request an exemption to 10 CFR 33.17(a)(4) to allow the manufacturing and distribution to specific licensees. To request for an exemption then:

   a. Confirm that only radioactive drugs for which the FDA has accepted an IND application will be manufactured and distributed under this exemption.
   b. Provide evidence that you are registered with the State or the FDA as a drug manufacturer.
   c. State the proposed exemption description and why it is needed.
   d. A description of specific compensatory safety measures that will provide a level of protection equivalent to the regulation for that the licensee-proposed exemption is being requested,
   e. A discussion of reasonable alternatives that have been considered by the Licensee; and
   f. Provide labeling and packaging information used for shipping IND materials.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 142708. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

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