



REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 4, 2009

Docket No. 03010814
Control No. 143601

License No. 29-02608-03

James Kwiatkowski
Manager - Environmental Health & Safety
Johnson & Johnson Pharmaceutical
Research & Development, LLC
1000 Route 202
Raritan, NJ 08869

SUBJECT: JOHNSON & JOHNSON PHARMACEUTICAL, REQUEST FOR ADDITIONAL
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO
LICENSE, CONTROL NO. 143601

Dear Mr. Kwiatkowski:

This is in reference to your letter dated April 28, 2009 requesting to amend Nuclear Regulatory Commission License No. 29-02608-03. In order to continue our review, we need the following additional information:

1. We have received your survey documentation for the decommissioning of your facility at 1001 U.S. Route 202 North, Raritan, New Jersey. This survey data as presented does not appear to be in sufficient type to demonstrate decommissioning. It appears only wipes were taken in the areas of use and many areas only provided counting information for carbon 14 and not for tritium. The guidance for decommissioning surveys can be found in NUREG-1757, Volume 1, Revision 2 and Volume 2, Revision 1. The simplified survey procedure can be found in Figure 8.1 on page 8-2 of NUREG-1757, Volume 1, Revision 2. Please submit surveys with wipe results annotating being counted for carbon 14 and tritium along with direct readings, scanning of surfaces with instrumentation information, and scanning methodology. Specifically state wipe results for both carbon 14 and tritium.
2. Prior to termination of a license, 10 CFR 30.35(g), 30.36(k)(4) and 30.51 require that you submit to the NRC certain records. Please confirm that the following records will be maintained for license termination or that you are not required to maintain these records for the 1001 U.S. Route 202 North, Raritan, New Jersey facility.
 - a. for unsealed materials with half-lives greater than 120 days, records for disposal made pursuant to 10 CFR 20.2002 (alternate disposal procedures, including burial authorized prior to January 28, 1981), 20.2003 (disposals to the sanitary sewerage system), 20.2004 (incineration of wastes), 20.2005 (disposal of specific wastes including liquid scintillation cocktail and animal tissue), and 20.2103(b)(4), evaluations of effluent releases.

- b. records important for decommissioning as described in 30.35(g), 40.36(f) and 70.25(g). Examples of such records include but are not limited to: records of contamination, identifying the radionuclides, quantities and concentrations; as-built drawings and modifications of structures and equipment in restricted areas and locations of inaccessible contamination such as buried pipes; a single list, updated at least every 2 years, of areas to which access is limited for the purpose of radiation protection (restricted areas); and records related to the provision of financial assurance.
- 3. In support of an environmental assessment related to the release of your facilities:
 - a. Provide the size of both buildings in square feet, and the area of material use at the North Brunswick, New Jersey facility.
 - b. Describe the type of building use such as "general office and laboratory" for each facility.
 - c. Describe the surrounding area, such as "residential", "industrial", "commercial", "mixed residential/commercial", etc. for each facility.
 - d. Describe the general type of activities authorized on the license, such as "laboratory procedures typically performed on bench tops and in hoods" for each facility.

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 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 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. 143601. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

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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