



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

March 23, 2011

Docket No. 03035937
Control No. 574639

License No. 06-30720-01

Cohava Geiber
Vice President Research and Development
MannKind Corporation
Building 8
One Casper Street
Danbury, CT 06810

SUBJECT: MANNKIND CORPORATION, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 574639

Dear Mr. Geiber:

This is in reference to your letter dated March 8, 2011 requesting to terminate Nuclear Regulatory Commission License No. 06-30720-01. In order to continue our review, we need the following additional information:

1. Your application should have been signed by a management representative rather than Mr. John Grimardi. Please submit a letter signed by a management representative indicating that management has reviewed the application and concurs in the statements and representations contained therein.
2. You have submitted surveys of areas with material use to show the absence of licensed material in your facility. However, surveys for all areas of use were not submitted. In your letter dated December 29, 2004, you had requested a change to your waste storage room. With this change the waste storage had moved and you had stated that direct reading measurements and detailed swipes analyzed by liquid scintillation counting were performed. Although those surveys for that area was not required at the time of the request, those surveys or current surveys showing that the area used was releasable, needs to be submitted at this time.
3. 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 submit the following records, or explain why such records are not applicable.
 - 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). 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.

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; 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. 574639. 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

cc:
John B. Grimardi, Radiation Safety Officer

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