



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

March 22, 2007

Docket No. 03037046
Control No. 140231

License No. 29-31097-01

Pedro Huertas, M.D.
Chief Development Officer
Amicus Therapeutics
6 Cedarbrook Drive
Cranbury, NJ 08512

SUBJECT: AMICUS THERAPEUTICS, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 140231

Dear Dr. Huertas:

This is in reference to your letter dated March 5, 2007 requesting to amend Nuclear Regulatory Commission License No. 29-31097-01. In order to continue our review, we need the following additional information:

1. Your amendment request was signed by Dr. David J. Lockhart, Chief Scientific Officer. If you wish to change the designated management representative for the NRC correspondence to Dr. David J. Lockhart, please make that request in a letter. Alternatively, please indicate that management has reviewed the amendment request and concurs in the statements and representations contained therein. Note also that the designated management representative should sign all future correspondence that requests a change in your license.
2. In support of your request for more than one millicurie of phosphorus-32, submit special safety instructions to be provided to individuals. Your procedures should include:
 - a. the use of low density shielding (e.g., plexiglass) in order to keep Bremsstrahlung radiation at a minimum,
 - b. a mandatory radiation survey and wipe test for radioactive contamination after each use,
 - c. the use of finger extremity monitors for procedures that involve one millicurie or more,
 - d. a dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures, and
 - e. the use of eye protection for procedures that involve 10 millicuries or more.

3. In support of your request for more than one millicurie of radioiodine, submit special safety instructions to be provided to individuals. Your procedures should include:
 - a. A mandatory radiation survey and wipe test for radioactive contamination after each use.
 - b. Bioassay procedures for individuals working with millicurie quantities of radioiodine.
 - c. The use of vented hoods for the storage of millicurie quantities of radioiodine.
 - d. A dry run prior to the performance of unfamiliar procedures in order to preclude unexpected complications. In addition, it is recommended that the radiation protection officer be present during new procedures.
 - e. Procedures for measuring the concentration of radioiodine from the hoods where material is stored.

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. 140231. 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 Thomas K. Thompson

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

cc:
Scott Dennerlein, Radiation Safety Officer

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SUNSI Review Complete: DLawyer

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