



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

July 11, 2006

Docket No. 03034092  
Control No. 139082

License No. 29-30285-01

S. James Lee, Ph.D.  
Vice President, Drug Development  
SK Bio-Pharmaceutical R&D Center  
Division of SK Energy and Chemical, Inc.  
140A New Dutch Lane  
Fairfield, NJ 07004

SUBJECT: SK BIO-PHARMACEUTICAL R&D CENTER, REQUEST FOR ADDITIONAL  
INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO  
LICENSE, CONTROL NO. 139082

Dear Dr. Lee:

This is in reference to your letter dated June 29, 2006 requesting to amend Nuclear Regulatory Commission License No. 29-30285-01. In order to continue our review, we need the following additional information:

1. Your amendment letter should have been signed by Dr. Lee, the management representative rather than the Radiation Safety Officer. 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. Note also that a management representative should sign all future correspondence that requests a change in your license.
2. Survey results were submitted for rooms 31, 32, 33, 34, 122, 126, 128, and 131. However, previously submitted documents shows that license material was authorized in Lab II, Metabolism Lab I, PK Lab-1, Animal Facility Room A1 and A5. These appear to have been room numbers 103, 105, 107, and 109. Please submit a site plan layout detailing the above named rooms and the room numbers used in the Decommissioning Survey prepared by Antkowiak and Mahoney Enterprises, Inc. Please explain any area that was not surveyed.
3. According to a letter dated August 18, 1997, Laboratory I was to be renovated. A smear test of the entire Laboratory I would be performed and documented prior to renovation. Please submit a copy of that survey.
4. In support of an environmental assessment related to the release of your facility:
  - a. Provide the name of the facility to be released
  - b. Provide the size of the building in square feet and the size of the area that allowed use of unsealed materials

- c. Describe the type of building use such as “general office and laboratory”
  - d. Describe the surrounding area, such as “residential”, “industrial”, “commercial”, “mixed residential/commercial”, etc.
  - e. Describe the general type of activities authorized on the license, such as “laboratory procedures typically performed on bench tops and in hoods.
  - f. State when you ceased licensed activities at the facility.
5. The mailing address of your license is the same as the facility that you are requesting to be removed from areas of material usage. Please state the mailing address to be used for all future NRC correspondence.

Current NRC regulations and guidance are included on the NRC’s website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page**. Or you may 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. 139082. 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:  
Lin-Ming Shen, Radiation Safety Officer

S. Lee  
SK Bio-Pharmaceutical R&D Center

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**SUNSI Review Complete: DLawyer**

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NAME	DLawyer/DRL							
DATE	07/11/2006							

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