



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

September 22, 2006

Docket No. 03034092
Control No. 139082

License No. 29-30285-01

S. James Lee, Ph.D.
VP, Drug Development
SK Bio-Pharmaceutical R&D Center
Division of SK Energy and Chemical, Inc.
22-10 State Route 208
Fairlawn, NJ 07410

SUBJECT: SK BIO-PHARMACEUTICAL R&D CENTER, LICENSE AMENDMENT,
CONTROL NO. 139082

Dear Dr. Lee:

This refers to your license amendment request. Enclosed with this letter is the amended license. The facility at 140A New Dutch Lane, Fairfield, New Jersey may be released for unrestricted use.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5239, so that we can provide appropriate corrections and answers.

The Notice of Availability of Environmental Assessment and Finding of No Significant Impact for this action was published on September 21, 2006, in the Federal Register, Volume 71, Number 183. A copy of the Federal Register Notice is enclosed for your information.

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 **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).

Thank you for your cooperation.

Sincerely,

Original signed by Dennis R. Lawyer

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

S. Lee
SK Bio-Pharmaceutical R&D Center

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Enclosure:
Amendment No. 10
Federal Register, Volume 71, Number 183, pages 55223-55225

cc:
Lin-Ming Shen, Ph.D., 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	09/22/2006							

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MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. SK Bio-Pharmaceutical R&D Center Division of SK Energy and Chemical, Inc.</p> <p>2. 22-10 State Route 208 Fairlawn, New Jersey 07410</p>	<p>In accordance with the letter received June 29, 2006,</p> <p>3. License number 29-30285-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date April 30, 2011</p> <p>5. Docket No. 030-34092 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Sulfur 35</p> <p>E. Iodine 125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Non-volatile Compounds</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 499 millicuries</p> <p>B. 49 millicuries</p> <p>C. 10 millicuries</p> <p>D. 10 millicuries</p> <p>E. 10 millicuries</p>
<p>9. Authorized use:</p> <p>A. through E. Research and development as defined in 10 CFR 30.4; animal studies.</p>		

CONDITIONS

10. Licensed material may be used or stored only at the licensee's facilities located at 22-10 State Route 208, Fairlawn, New Jersey.
11. A. Licensed material shall be used by, or under the supervision of Hongwook Kim, Ph.D. or Lin-Ming Shen, Ph.D.
- B. Licensed material in items 6.A., 6.B., and 6.D. may also be used by, or under the supervision of James T. Yang, Ph.D.
- C. The Radiation Safety Officer for this license is Lin-Ming Shen, Ph.D.

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12. Licensed material shall not be used in or on human beings except as provided otherwise by specific condition of this license.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
15. The licensee is authorized to hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it:
 - A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
16. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

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17. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U. S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 27, 1996 [ML061440193]
- B. Letter dated May 7, 1996 [ML061440198]
- C. Letter dated June 10, 1996 [ML061440199]
- D. Letter dated January 16, 1997 [ML061440203]
- E. Letter dated February 19, 1997 [ML061440208]
- F. Letter dated August 18, 1997 [ML061440211]
- G. Letter dated August 31, 1999 with attachment dated August 27, 1999 [ML061440214]
- H. Letter dated March 7, 2001 [ML010720436]
- I. Letter dated April 11, 2001 [ML011100245]
- J. Letter dated January 8, 2003 [ML030170382]
- K. Letter dated February 24, 2003 [ML030620184]

For the U.S. Nuclear Regulatory Commission

Date September 22, 2006

By

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406