



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

February 10, 2005

Docket No. 03035937
Control No. 136229

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, ISSUANCE OF LICENSE AMENDMENT,
CONTROL NO. 136229

Dear Mr. Geiber:

This refers to your license amendment request. Enclosed with this letter is the amended license.

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.

An environmental assessment for this action is not required, since this action is categorically excluded under 10 CFR 51.22(c)(14).

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Thank you for your cooperation.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:

C. Geiber
MannKind Corporation

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Amendment No. 4

cc:
John G. Rimardi, Radiation Safety Officer

DOCUMENT NAME: E:\Filenet\ML050410477.wpd

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OFFICE	DNMS/RI	N	DNMS/RI	DNMS/RI			
NAME	TThompson /TKT/						
DATE	2/10/05						

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MATERIALS LICENSE

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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. MannKind Corporation</p> <p>2. One Casper Street - Building 8 Danbury, Connecticut 06810</p>	<p>In accordance with the letter dated December 29, 2004,</p> <p>3. License number 06-30720-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date March 31, 2012</p> <p>5. Docket No. 03035937 Reference No.</p>
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<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Iodine 125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Non-volatile Compounds</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 25 millicuries</p> <p>B. 20 millicuries</p> <p>C. 55 millicuries</p>
<p>9. Authorized use:</p> <p>A. Through C. Research and development as defined in 10 CFR 30.4.</p>		

CONDITIONS

- 10. Licensed material may be used or stored only at the licensee's facilities located at One Casper Street, Building 8, Danbury, Connecticut.
- 11. Licensed material shall be used by, or under the supervision of, Rodrigo T. Laureano, John Grimardi, or Bryan R. Wilson.
- 12. The Radiation Safety Officer for this license is John Grimardi.
- 13. The licensee shall not use licensed material in or on human beings.

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**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
06-30720-01

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Amendment No. 04

- 14. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.
- 15. The licensee is authorized to hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal in ordinary trash, provided:
 - A. Waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.
 - B. Before disposal as ordinary trash, the waste shall be surveyed at the container surface with the appropriate survey instrument set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.
 - C. A record of each such disposal permitted under this license condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate 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."
- 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. Letter dated March 4, 2002 with enclosure (ML020670211)
 - B. Letter dated December 29, 2004 (ML050180356)

For the U.S. Nuclear Regulatory Commission

Original signed by Thomas K. Thompson

Date February 10, 2005

By _____

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

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