



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

December 27, 2007

Docket No. 03035590
Control No. 141389

License No. 29-30602-01

Stuart Peltz, Ph.D.
President and CEO
PTC Therapeutics, Inc.
100 Corporate Court
Middlesex Business Center
South Plainfield, NJ 07080-2449

SUBJECT: PTC THERAPEUTICS, INC., LICENSE AMENDMENT, CONTROL NO. 141389

Dear Dr. Peltz:

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

In addition to your request, license condition number 16 was modified to the current guidance. For background information please see <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2004/ri200417r1.pdf>

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).

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 1-866-512-1800. 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. Peltz
PTC Therapeutics, Inc.

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Enclosure:
Amendment No. 2

cc:
Richard Lipman, Radiation Safety Officer

DOCUMENT NAME: C:\FileNet\ML080060002.wpd

SUNSI Review Complete: DLawyer

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NAME	DLawyer/DRL							
DATE	12/27/2007							

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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 style="text-align: center;">Licensee</p> <p>1. PTC Therapeutics, Inc.</p> <p>2. 100 Corporate Court Middlesex Business Center South Plainfield, New Jersey 07080-2449</p>	<p>In accordance with the letter dated November 16, 2007,</p> <p>3. License number 29-30602-01 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date January 31, 2011</p> <hr/> <p>5. Docket No. 030-35590 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. Phosphorus 32</p> <p>D. Phosphorus 33</p> <p>E. Sulfur 35</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. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 30 millicuries</p> <p>B. 10 millicuries</p> <p>C. 40 millicuries</p> <p>D. 20 millicuries</p> <p>E. 20 millicuries</p>
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9. Authorized use:

A. Through E. Research and development as defined in 10 CFR 30.4.

CONDITIONS

- 10. Licensed material may be used only at the licensee's facilities located at 100 Corporate Court, Middlesex Business Center, South Plainfield, New Jersey.
- 11. A. Licensed material shall be used by, or under the supervision of, Gregory Ryan, Ph.D., Richard Lipman, Ph.D., or Jana Narasimhan, Ph.D.
- B. Licensed material in items 6.C. and 6.D., may also be used by, or under the supervision of, Sergey Paushkin, Ph.D.
- 12. The Radiation Safety Officer for this license is Richard Lipman, Ph.D.
- 13. Licensed material shall not be used in or on human beings.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
29-30602-01

Docket or Reference Number
030-35590

Amendment No. 2

14. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
15. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
16. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- 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.
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 October 25, 2000 (ML003771111)
 - B. Letter dated November 16, 2007 (ML073410632)

For the U.S. Nuclear Regulatory Commission

Date December 27, 2007

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