



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

January 31, 2005

Docket No. 030-31689  
Control No. 135721

License No. 19-07538-05

Jerry M. Collins, Ph.D.  
Director  
Laboratory of Clinical Pharmacology  
Office of Testing and Research  
Center for Drug Evaluation and Research, FDA, DHHS  
Life Sciences Building #64, Room 2022  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

SUBJECT: LABORATORY OF CLINICAL PHARMACOLOGY, APPLICATION FOR  
LICENSING ACTION, CONTROL NO. 135721

Dear Dr. Collins:

This refers to your license amendment request. Enclosed with this letter is the amended license. The facility located at 5516 Nicholson Lane, Kensington, Maryland 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.

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 [pdf@nrc.gov](mailto:pdf@nrc.gov).

Thank you for your cooperation.

Sincerely,

***Original signed by Bryan A. Parker***

Bryan A. Parker  
Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

J. Collins  
Laboratory of Clinical Pharmacology

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Enclosure:  
Amendment No. 7

DOCUMENT NAME: E:\Filenet\ML050350074.wpd

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	BParker/BAP							
DATE	1/31/2005							

OFFICIAL RECORD COPY

**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. Laboratory of Clinical Pharmacology Office of Testing and Research Center of Drug Evaluation and Research</p> <p>2. U. S. Food and Drug Administration, DHHS Life Sciences Building #64, Room 2022 10903 New Hampshire Avenue Silver Spring, MD 20993</p>	<p>In accordance with the letter dated September 21, 2004,</p> <p>3. License No. 19-07538-05 is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration Date: July 31, 2005</p> <hr/> <p>5. Docket No. 030-31689</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 90 millicuries</p> <p>B. 90 millicuries</p>
<p>9. Authorized use:</p> <p>A. and B. 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 the Life Sciences Building #64, 10903 New Hampshire Avenue, Silver Spring, Maryland.
11. Licensed material shall be used by, or under the supervision of, Jerry M. Collins, Ph.D., Aspandiar S. Katki, Raymond W. Klecker, Edward Radden, Robert Parker, Ph.D., John Strong, Ph.D., Neil Hartman, Ph.D., Lawrence Anderson, Ph.D., and Richard Cysyk, Ph.D..
12. The Radiation Safety Officer (RSO) for this license is Raymond W. Klecker.
13. Licensed material shall not be used in or on human beings.

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**License No.  
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030-31689Amendment No.  
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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. Experimental animals, or the products from experimental animals, that have been administered licensed materials shall not be used for human consumption.
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. Application dated April 25, 1995
  - B. Letter dated July 21, 1995
  - C. Letter dated December 3, 1997
  - D. Letter dated January 21, 1998
  - E. Letter received December 22, 1999
  - F. Letter dated March 23, 2000
  - G. Letter dated July 3, 2001
  - H. Letter dated July 25, 2003
  - I. Letter dated September 22, 2003
  - J. Letter dated September 21, 2004 [ML042680142]

For the U. S. Nuclear Regulatory Commission

***Original signed by Bryan A. Parker***Date January 31, 2005  
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Bryan A. Parker  
Commercial and R&D Branch  
Division of Nuclear Materials Safety  
Region I  
King of Prussia, Pennsylvania 19406