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## Global Research & Development

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Mr. Steven Courtemanche  
Division of Nuclear Material Safety  
U.S. Nuclear Regulatory Commission  
475 Allendale Road  
King of Prussia, PA 19406-1415

RE: Docket No. 03036825  
Control No. 136330  
License No. 06-30933-02

Dear Mr. Courtemanche,

I am writing in response to the questions in your letter dated March 21, 2005 regarding our application for a radioactive materials license for the Pfizer New Haven Clinical Research Unit. I have numbered our responses below to correspond to the numbers of the questions in your letter.

1. We intend to perform studies for various Investigational New Drugs (INDs). We understand that NRC policy requires us to submit a license amendment for approval prior to beginning a study with each new IND under 10 CFR 35.100.

The first study we intend to conduct will involve the following IND:

- a) FDA IND number: 69,687
  - b) Isotope: Carbon-14
  - c) Chemical Form: Any
  - d) Max Activity to be possessed: 60 mCi
  - e) Licensed material will be obtained from Pfizer Global Research and Discovery, Groton, Connecticut, NRC Licensed No. 06-05869-01.
2. Irina V. Kaplan, Ph.D. and Joyce Van Winkle, D.P.M., may supervise licensed activities under 10 CFR 31.11. Thomas E. Murtaugh, M.D. may supervise operations under 10 CFR 31.11 and 10 CFR 35.100.
  3. Dr. Murtaugh was an Authorized Supervisor under the State of Wisconsin Radioactive Material License Number 025-1075-01. Under this license, Dr. Murtaugh performed uptake, dilution and excretion studies on human patients

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using H-3 and C-14. Dr. Murtaugh is also licensed to practice medicine in the State of Connecticut.

A copy of the Wisconsin license and his Connecticut licensing status are provided in Attachment 1 to this letter. Dr. Murtaugh's resume was submitted in the application dated January 7, 2005.

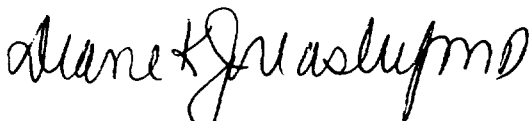
4. We will only handle unit dosages of loose radioactive material at the New Haven Clinical Research Unit. In accordance with 10 CFR 35.63, we do not intend to perform direct measurements of radioactivity to determine dosage but rather will use a decay correction, based on the activity or activity concentration determined by –
  - a) A manufacturer or preparer licensed under 10 CFR 32.72 or equivalent Agreement State requirements; or
  - b) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.
5. Please revise Item 10H. on page 8 of our application dated January 7, 2005 to read as follows:

Safe Use of Unsealed Licensed Material

Pfizer has developed and will implement and maintain instructions for the safe use of unsealed licensed materials that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

I hope that I have satisfactorily addressed all of your questions. If you have any additional questions or concerns, please contact me at 860-732-0805. I have taken over management responsibility for the Radiation Safety Program from Walid Abi-Saab, Ph.D. so please direct any reply to my attention.

Sincerely,



Diane K. Jorkasky, MD

Vice President

Global Clinical Pharmacology and Clinical Research Units

Enclosure

**Attachment 1**

**Authorized Supervisor Qualifications  
Thomas E. Murtaugh, M.D.**



**STATE OF WISCONSIN  
DEPARTMENT OF HEALTH AND FAMILY SERVICES**

representations made by the licensee, a license is issued authorizing the licensee to receive, acquire, possess and transfer radioactive material designated below; to use the material for the purpose(s) and at the place(s) designated below; and to deliver or transfer the material to persons authorized to receive it in accordance with Chapter HFS 157, Wisconsin Administrative Code. This license is subject to all applicable rules and orders of the Wisconsin Department of Health and Family Services (DHFS) including Chapter HFS 157, Wisconsin Administrative Code now or hereafter in effect, and to any conditions specified below.

<b>Licensee Name and Address</b>		<b>In accordance with application dated July 30, 2004</b>	
<b>1. Covance Clinical Research Unit, Inc.</b>		<b>3. License Number: 025-1075-01</b>	
<b>2. 3402 Kinsman Boulevard</b>		<b>is amended in its entirety to read as follows:</b>	
<b>form</b>		<b>4. Amendment No: 02</b>	
<b>5. Exemption Data:</b>		<b>6. Authorized Use:</b>	
<b>A. Limited to carbon-14</b>		<b>A. Any radiopharmaceutical identified in HFS 157.63(1)</b>	
<b>B. Limited to hydrogen-3</b>		<b>B. Any radiopharmaceutical identified in HFS 157.63(1)</b>	

**CONDITIONS**

10. Licensed material may be received, used and stored only at the licensee's facilities located at 3402 Kinsman Boulevard, Madison, WI. 53704
12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user in accordance with HFS 157.13(5)(b) and HFS 157.13(5)(c).

DPH 45018 (07/03)

**RADIOACTIVE MATERIALS  
LICENSE  
SUPPLEMENTARY SHEET**

License Number: 025-1075-01

Amendment No: 02

B. The following individuals are authorized users for the materials and uses indicated:

<u>Authorized Users</u>	<u>Materials and Use</u>
1. Russell M. Dixon, M.D.	Carbon-14 and hydrogen-3 for human research studies.
2. William Bridson, M.D.	Carbon-14 and hydrogen-3 for human research studies.
3. Thomas E. Murtaugh, M.D.	Carbon-14 and hydrogen-3 for human research studies.

C. The Authorized Nuclear Pharmacist for this license is Richard Hammes, R.Ph.

13. The licensee is authorized to transport licensed material in accordance with the provisions of Chapter HFS 157, 'Radiation Protection', Subchapter VIII, 'Transportation', and all sections of HFS 157, Subchapter VI, "Medical Use of Radioactive Material".
15. 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, except for minor changes in the medical use radiation safety procedures as provided in HFS 157.61. Chapter HFS 157, 'Radiation Protection' shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rule.

A. Application dated July 30, 2004, with attachments, and signed by Chris Ore.

SIGNATURE

FOR THE HFS COMPTROLLER

Materials Program Supervisor

DATE

10/01/04

Connecticut Licensing

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## Health Care or Environmental Health Professional's License Status

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This site is part of CT-clc.com, the Connecticut Licensing Info Center, that links to all YOUR State licensing and registration needs.

Note: Requests for copies of documents related to past disciplinary action must be submitted in writing. Such documents are currently not available in an electronic format. Therefore, include your name, mailing address and telephone number on any request.

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**License Type:** Physicians & Surgeons  
**License Number:** 043238  
**Name:** MURTAUGH, THOMAS  
**Expiration Date:** 12/31/2005  
**Granted Date:** 3/24/2005  
**License Name:** Thomas Edward Murtaugh M.D.  
**License Status:** Current  
**Disciplinary Action:** None

Questions ? ?

E-mail [webmaster.dph@po.state.ct.us](mailto:webmaster.dph@po.state.ct.us) or call (860) 509-7803  
[Return to DPH Licensing/Renewal Page](#)

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For Business Registry Questions? Contact **SmartStart** or call 1-800-382-2122.

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03/29/2005