

March 10, 2005

U.S. Nuclear Regulatory Commission  
Region I  
Nuclear Materials Safety Branch  
475 Allendale Road  
King of Prussia, PA 19406-1415

03032971

**RE:** Radioactive Material License #24-04206-16MD (Wilkes-Barre Nuclear Pharmacy)

***Please Expedite Licensing Action***

Dear License Reviewer:

Please amend the above-referenced radioactive materials license as follows:

- Replace Attachment B of letter dated June 18, 2004 regarding the current license application with the data contained in Attachment A. New, as well as improved existing, unit and bulk dose shielding have been put into service. In addition, we request that future submittals regarding unit and bulk dose shielding be required only if changes to shielding will increase the radiation levels at the surface of the container. All data will be maintained on file and available for inspection.

All primary shields will be shipped in packaging that meets the requirements of Title 49 Code of Federal Regulations.

- We request that future submittals with regard to the prescription label provided in Appendix H of the current license application be limited to changes in labeling that will cause a change to radioactive markings or labeled activity, other than position and size of symbols and wording.

All other items relating to this radioactive material license remain unchanged at this time.

REC'D IN LAT 3/14/2005

136612  
NMSS/RGNI MATERIALS-002

Please contact April Chance at (314) 654-7960 if you have any questions and/or require supplemental information regarding this request. Your prompt review and approval of this licensing action is greatly appreciated.

Sincerely,



Kay M. Yodet

Director, Radiation, Environment, Health & Safety – Mallinckrodt Inc.

Attachments

cc: K. Pieszala, Nuclear Pharmacy Manager (Wilkes-Barre, PA)  
M. Loiseau, Radiation Safety Officer (Wilkes-Barre, PA)  
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)  
J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

**ATTACHMENT A  
RADIATION PROFILE DATA**

| <b>Nuclide</b> | <b>Maximum Activity<br/>per Carrier<br/>(mCi)</b> | <b>Carrier</b> | <b>Maximum Radiation<br/>Field@ Surface<br/>(mR/hr)</b> |
|----------------|---|----------------|---|
| Technetium-99m | 1000  | Syringe        | 5   |
| Technetium-99m | 1500  | Vial           | 2.5   |
| Gallium-67     | 16  | Syringe        | 65  |
| Gallium-67     | 30  | Vial           | 20  |
| Thallium-201   | 9   | Syringe        | 10  |
| Thallium-201   | 16  | Vial           | 8   |
| Iodine-131     | 44  | Vial           | 90  |
| Iodine-131     | 630   | Vial           | 475   |
| Xenon-133      | 150   | Vial           | 15  |

This is to acknowledge the receipt of your letter/application dated

3/10/2005, and to inform you that the initial processing which includes an administrative review has been performed.

Amend. 24-04206-16M11 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 136612.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.

BETWEEN: : (FOR LFMS USE)  
 : INFORMATION FROM LTS  
 : -----  
 :  
 License Fee Management Branch, ARM : Program Code: 02500  
 and : Status Code: 0  
 Regional Licensing Sections : Fee Category: 3C 2B  
 : Exp. Date: 20140630  
 : Fee Comments: \_\_\_\_\_  
 : Decom Fin Assur Req'd: N  
 : .....

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED  
 Applicant/Licensee: MALLINCKRODT INC.  
 Received Date: 20050314  
 Docket No: 3032971  
 Control No.: 136612  
 License No.: 24-04206-16MD  
 Action Type: Amendment

2. FEE ATTACHED  
 Amount:             
 Check No.:           

3. COMMENTS

Signed *[Signature]*  
 Date 3/21/05

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /\_/)

- 1. Fee Category and Amount: \_\_\_\_\_
- 2. Correct Fee Paid. Application may be processed for:
  - Amendment \_\_\_\_\_
  - Renewal \_\_\_\_\_
  - License \_\_\_\_\_
- 3. OTHER \_\_\_\_\_

Signed \_\_\_\_\_  
 Date \_\_\_\_\_