

March 10, 2005

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

03032951

RE: Radioactive Material License #24-04206-14MD (Pine Brook Nuclear Pharmacy)

Please Expedite Licensing Action

Dear License Reviewer:

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

- Replace Appendix H of 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.

- Update Appendix G of the current license application with the information provided in Attachment B. In addition, we request that future submittals be limited to changes to 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

136607
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. Yoder

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



Attachments



cc: Z. Sheng, Interim Nuclear Pharmacy Manager (Pine Brook, NJ)
M. Marinock, Radiation Safety Officer (Pine Brook, NJ)
A. Chance, Manager, Radiological Affairs (Hazelwood, MO)
J. Schuh, Manager, EHS, Pharmacy Operations (Hazelwood, MO)

**ATTACHMENT A
RADIATION PROFILE DATA**

Nuclide	Maximum Activity per Carrier (mCi)	Carrier	Maximum Radiation Field@ Surface (mR/hr)
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

ATTACHMENT B SAMPLE LABELS

TC - 99M MYOVIEW (TETROFOSMIN) Item: R499A0 Lot: 61495	TC - 99M MYOVIEW (TETROFOSMIN)	
	Procedure: MYOCARDIAL IMAGING	
	Activity: 25 mCi @ 08:45 4 MAR 2005 FRI	
	Vol: 1.33 ml	Use By: 12:30 4 MAR 2005 FRI
	Conc: 18.7999 mCi / ml	Dispensed: 4 MAR 2005 FRI
	Issued: 4 MAR 2005 FRI	
DIAGNOSTICS & CLINICAL CARDIO		
ATTN NUCLEAR MEDICINE 769 NORTHFIELD AVENUE SUITE 220 W ORANGE, NJ 07052		
Pt: M.D. USE	Weight: [REDACTED]	
Dr: SABINO R. TORRE, M.D.		
License: 29-30448-01	Procedure Instructions Rx: 00484977	
PO: [REDACTED]		
NDC: [REDACTED]		
MALLINCKRODT		
(800) 261-0811		
26 CHAPIN ROAD UNIT 1110		
PINE BROOK, NJ 07068		
RPH: DENISE A CALLENDER		
RX ONLY		
		
		

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TC-99M MYOVIEW (TETROFOSMIN)
MYOCARDIAL IMAGING
25 mCi @ 08:45 4 MAR 2005 FRI
MALLINCKRODT/26 CHAPIN ROAD UNIT 1110
PINE BROOK
(800) 261-0811
Pt: M.D. USE



THE U.S. NUCLEAR REGULATORY COMMISSION HAS
APPROVED DISTRIBUTION OF THIS
RADIOPHARMACEUTICAL TO PERSONS LICENSED TO
USE BY PRODUCT MATERIAL LISTED IN PARAGRAPH
35.100, 200 & 300 OF 10 CFR PART 35
AND TO PERSONS HOLDING AN EQUIVALENT
LICENSE ISSUED BY AN AGREEMENT STATE.





Example Unit Dose Labels

TC - 99M SODIUM PERTECHNETATE Item: R005A0 Lot: 61564	TC - 99M SODIUM PERTECHNETATE	
	Procedure: FOR RADIOPHARMACEUTICAL USE	
	Activity: 50 mCi @ 19:00 4 MAR 2005 FRI	
	Vol: 0.51 ml	Use By: 06:35 5 MAR 2005 SAT
	Conc: 87.8789 mCi / ml	Dispensed: 4 MAR 2005 FRI
	Issued: 4 MAR 2005 FRI	
DIAGNOSTICS & CLINICAL CARDIO		
ATTN NUCLEAR MEDICINE 769 NORTHFIELD AVENUE SUITE 220 W ORANGE, NJ 07052		
Pt: M.D. USE	Weight: [REDACTED]	
Dr: SABINO R. TORRE, M.D.		
License: 29-30448-01	Procedure Instructions Rx: 00484982	
PO: [REDACTED]		
NDC: [REDACTED]		
MALLINCKRODT		
(800) 261-0811		
26 CHAPIN ROAD UNIT 1110		
PINE BROOK, NJ 07068		
RPH: BARBARA D SCAVULLO		
RX ONLY		
		
		

TC-99M SODIUM PERTECHNETATE
FOR RADIOPHARMACEUTICAL USE
50 mCi @ 19:00 4 MAR 2005 FRI
MALLINCKRODT/26 CHAPIN ROAD UNIT 1110
PINE BROOK
(800) 261-0811
Pt: M.D. USE



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35.100, 200 & 300 OF 10 CFR PART 35
AND TO PERSONS HOLDING AN EQUIVALENT
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Example Bulk Dose Labels

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.

Amendment 24-04206-14MD
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

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** 136607.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

: (FOR LFMS USE)
 : INFORMATION FROM LTS
 : -----
 :
 BETWEEN: :
 :
 License Fee Management Branch, ARM : Program Code: 02500
 and : Status Code: 0
 Regional Licensing Sections : Fee Category: 3C 2B
 : Exp. Date: 20130331
 : Fee Comments: 3P DEL 3/19/99
 : Decom Fin Assur Reqd: N
 : ::

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 Applicant/Licensee: MALLINCKRODT INC.
 Received Date: 20050314
 Docket No: 3032951
 Control No.: 136607
 License No.: 24-04206-14MD
 Action Type: Amendment

2. FEE ATTACHED
 Amount:
 Check No.:

3. COMMENTS
 Signed *Rebecca J. Smith*
 Date 3/18/2005

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 _____