Mallinckrodt
Pharmaceuticals

Via Federal Express

February 22, 2016

Bryan Parker
Materials Licensing Section
United States Nuclear Regulatory Commission – Region III
2442 Warrenville Road, Suite 210
Lisle, IL 60352-4352

RE: Notification of Asset Transfer
NRC Letter to Mallinckrodt dated October 27, 2015
Mallinckrodt letter to NRC dated September 21, 2015
NRC Licenses 24-04206-01, 24-04206-02 and 24-04206-05MD

Dear Mr. Parker:

This letter is to notify the Nuclear Regulatory Commission (NRC) that Mallinckrodt plc has completed an internal corporate reorganization as described in our letter to the NRC dated September 21, 2015. As a result of that reorganization all assets associated with the licenses listed in Exhibit A have been transferred to a new legal entity known as Mallinckrodt Nuclear Medicine LLC. This transaction was effective January 22, 2015. As a result of the transaction Mallinckrodt is submitting this license amendment request to amend the name of the licensee from Mallinckrodt LLC to Mallinckrodt Nuclear Medicine LLC.

If you have any questions regarding this amendment request please do not hesitate to contact me at (314)654-7981.

Sincerely,

James R. Schuh

James R. Schuh
Director, EHS – Nuclear Operations

Enc:

Exhibit A – Permit List

cc: Eric Berry (Mallinckrodt)
Manuel Diaz (Mallinckrodt)
Debbie Piskura (USNRC – RIII)
Sumit Verma (Mallinckrodt)

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Mallinckrodt
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Exhibit A
List of Impacted Mallinckrodt LLC Licenses

24-04206-01
24-04206-02
24-04206-05MD

NRC FORM 313 (02-2016) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 **EXPIRES: 02/29/2016**

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy, and Information Collections Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR *(Check appropriate item)*

- [ ] A. NEW LICENSE
- [x] B. AMENDMENT TO LICENSE NUMBER 24-04206-05MD
- [ ] C. RENEWAL OF LICENSE NUMBER

2. NAME AND MAILING ADDRESS OF APPLICANT *(Include ZIP code)*

Mallinckrodt Nuclear Medicine LLC
2703 Wagner Place
Maryland Heights, MO 63043

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

2703 Wagner Place
Maryland Heights, MO 63043

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

James R. Schuh

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
(314) 654-7981	(314) 393-4558

BUSINESS EMAIL ADDRESS

James.Schuh@Mallinckrodt.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL
   a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*) *(See 10 CFR 170 and Section 170.31)*

FEE CATEGORY [ ] AMOUNT ENCLOSED $ [ ]

13. CERTIFICATION. *(Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.*

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35 , 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Sumit Verma / Site Director		22 FEB 16

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED $	CHECK NUMBER	COMMENTS
APPROVED BY				DATE	

SHIPPING ORDER
(NON-HAZARDOUS GOODS)

SHIP TO	ORIGINATOR	ORDER NO.
Bryan Parker Materials Licensing Section U.S. NRC Region III 2442 Warrenville Rd. Ste 210 Lisle IL, 60532-4352	Jim Schuh	027238
	DEPARTMENT EHS Director	SHIPPED FROM
	TELEPHONE EXT 6547806	MALLINCKRODT, INC. 2703 WAGNER PL. MARYLAND HTS., MO 63043
	DATE ISSUED ~~2/22/16~~ 3-15-16	
ROUTING FEX	ACCOUNT NO. (20 DIGIT) 011-010-08-0033	

DELIVERY INSTRUCTIONS

☒ NEXT DAY DELIVERY ☐ SECOND DAY DELIVERY ☐ OTHER (SPECIFY)

TRAFFIC APPROVAL	DATE	PIC/PURCHASING APPROVAL	DATE	SHIPPED DATE
[illegible]	15 MAR 16			

IMPORTANT NOTICE:
IF YOU THINK THE MATERIALS BEING SHIPPED QUALIFIES, OR MAY POSSIBLY QUALIFY, AS ANY ONE OF THE HAZARD CLASSES LISTED BELOW, REFER TO HAZARDOUS MATERIAL SHIPPING ORDER J-625.
EXPLOSIVES, FLAMMABLE GAS, FLAMMABLE LIQUID, FLAMMABLE SOLID, OXIDIZING SUBSTANCES, POISONOUS AND INFECTIOUS SUBSTANCES, RADIOACTIVE, CORROSIVES, MISC. DANGEROUS GOODS.

STORE ROOM MATERIAL

CODE	INDEX	LOCATOR	LOT NO.	DESCRIPTION	QTY. REQ'D	QTY. FILLED	EXTENSION

TOOLS/EQUIPMENT/MECH SUPPLIES REPAIR

QUANTITY	DESCRIPTION	ASSET OR ITEM NO.

MISCELLANEOUS MATERIAL

QUANTITY	DESCRIPTION (BE SPECIFIC)
1	Letter

MK 15385 (R 2/89) J-302

PACKING LIST

FedEx Express

earthsmart
FedEx carbon-neutral envelope shipping

Align top of FedEx Express shipping label here.

ORIGIN ID:ZSVA (800) 525-3689
SHIPPING DEPT.
MALLINCKRODT NUCLEAR MEDICINE LLC.
2703 WAGNER PLACE

MARYLAND HEIGHTS, MO 63043
UNITED STATES US

SHIP DATE: 15MAR16
ACTWGT: 0.1 LB
CAD: 0052080/CAFE2915

BILL SENDER

TO US NRC REGION III / BRYAN PARKER
MATERIALS LICENSING SECTION
2443 WARRENVILLE RD
STE 210
LISLE IL 605324537
REF: 027238

DEPT: SHIPPING

FedEx Express

TRK# 0201 9042 4662 1697

WED - 16 MAR 10:30A
PRIORITY OVERNIGHT

XH ENLA

60532
IL-US ORD

Part # 156148-434 NRIT V3 10-09

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