



April 9, 2019

Bryan Parker, Senior Health Physicist
Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road
Lisle, IL 60532

Re: Notification to NRC and Request for Approval to Change of Control of Materials License
Number 24-17450-01 held by Mallinckrodt LLC

Dear Mr. Parker:

This letter is to notify you that, on June 28, 2019, Mallinckrodt Pharmaceuticals intends to complete an intracompany reorganization that will result in certain assets and liabilities associated with the innovative specialty pharmaceutical brands business of Mallinckrodt Pharmaceuticals being transferred from Mallinckrodt LLC to Mallinckrodt Enterprises LLC.

Mallinckrodt LLC currently holds the above-referenced materials license (subsequently referred to as "license"), and owns legal title to the facility and equipment subject to the license. The facility that is subject to the license is located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042. As part of the above-described intracompany reorganization, Mallinckrodt LLC intends to transfer the license, as well as operation of the real property and equipment subject to the license, to Mallinckrodt Enterprises LLC. Mallinckrodt Enterprises LLC is the corporate parent of Mallinckrodt LLC, and both Mallinckrodt Enterprises LLC and Mallinckrodt LLC are wholly-owned, indirect subsidiaries of Mallinckrodt plc. Other than as described in the immediately preceding sentences, no changes are anticipated to the licensed property, equipment, or program.

By this letter, Mallinckrodt LLC is requesting NRC's consent to this change of control in connection with the above-referenced intracompany reorganization. In accordance with NUREG-1556, Volume 15, Revision 1, Appendix E, Mallinckrodt provides the following information to assist the NRC in evaluating this request for approval to this change of control.

1. Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.

We anticipate that, effective June 28, 2019, via an intracompany Business Transfer Agreement, Mallinckrodt LLC will transfer, assign, convey, and deliver to Mallinckrodt Enterprises LLC, and Mallinckrodt



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Enterprises LLC will accept and acquire from Mallinckrodt LLC, all of Mallinckrodt LLC's rights, title, and interests in and to the innovative specialty pharmaceutical brands business of Mallinckrodt Pharmaceuticals. As a result of this anticipated intracompany transfer, the licensee of the above-referenced licenses will be Mallinckrodt Enterprises LLC. Contact information for the licensee will remain as:

Mallinckrodt Enterprises LLC
Research and Development
675 McDonnell Boulevard
Hazelwood, Missouri 63042
Attention: Scott Surovi
Phone: (314) 654-7444

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel and any changes in the training program.

There are no changes anticipated in personnel or duties that relate to the licensed program. Scott J. Surovi shall remain as the Radiation Safety Officer.

3. Describe any changes in the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.

There are no changes anticipated to the licensed facility, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program.

4. Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.

Mallinckrodt Enterprises LLC will obtain and maintain possession of the facility in its current condition, because the facility will continue licensed operations. There are no changes anticipated to the licensed facility, equipment, or radiation safety program as a result of the above-described transfer. Mallinckrodt Enterprises LLC will assume full liability for final decommissioning of the above-referenced facility if it is shut down at any time in the future. All documentation concerning instrument calibration, sealed source inventory and leak testing, routine radiological tests and assessments, training, quality control and related records will be transferred to Mallinckrodt Enterprises LLC.



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5. If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm that all financial assurance instruments associated with the license will be held in the transferee's name before the license is transferred, and as required by 10 CFR 30.35(f), the licensee must, within 30 days, submit financial instruments reflecting such changes.

This item is not applicable.

6. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.

All records concerning the safe and effective decommissioning of the facilities will be transferred to Mallinckrodt Enterprises LLC.

7. Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.

Mallinckrodt LLC and Mallinckrodt Enterprises LLC both agree to the above-described transfer of control of the licensed material and activity, and to the conditions of said transfer. There are no open inspection items associated with the current license.

8. Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

Mallinckrodt Enterprises LLC agrees to perform and abide by all of the constraints, conditions, requirements, representations and commitments identified in the above-referenced license.



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9. The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts

This item is not applicable, as the facility is not a fuel cycle facility/licensee.

Please note that we would appreciate your expeditious review, evaluation and consent, if necessary, to complete the transaction. We are prepared to discuss in more detail or provide additional information to support your review. If you have any questions regarding the foregoing, please contact Scott Surovi at (314) 654-7444 or scott.surovi@mnk.com. Thank you for your assistance in this process.

Sincerely,

Richard Fitch, Ph.D.
Director Pharmacology
Mallinckrodt Research and Development

cc: Scott Surovi, Mallinckrodt
Cathi Ponciroli, Mallinckrodt

ORIGIN ID:ALNA (314) 654-3288
BARBARA MILLER
MALLINCKRODT LLC
675 MCDONNELL BLVD

SHIP DATE: 09APR19
ACTWGT: 1.00 LB
CAD: 111003219/INET4100

HAZELWOOD, MO 63042
UNITED STATES US

BILL SENDER

TO **BRYAN PARKER, SR. HEALTH PHYSICIST**
US NUCLEAR REGULATORY COMMISSION
2443 WARRENVILLE ROAD
MATERIALS LICENSING BRANCH

565J1D7E5Z3AD

LISLE IL 60532

(630) 829-9500

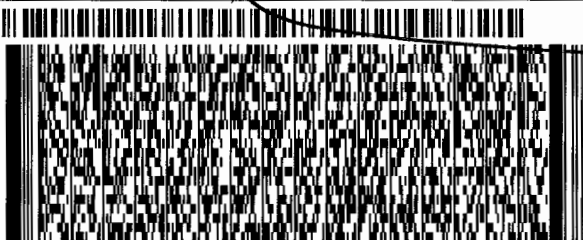
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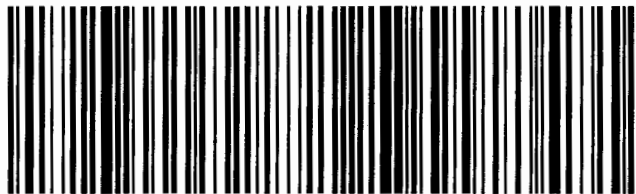
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