CAPVEST

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September 2, 2016

Patricia Pelke, Chief
Materials Licensing Branch
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

SUBJECT: Application for Approval of Transfer of Control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD

Dear Ms. Pelke,

Pursuant to 10 C.F.R. § 30.34(b), Mallinckrodt plc ("Mallinckrodt"), an Irish domiciled company with certain U.S. operations in St. Louis, Missouri, and CapVest Partners LLP ("CapVest"), a United Kingdom partnership, hereby request written approval by the U.S. Nuclear Regulatory Commission ("NRC") for the proposed transfer of control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD ("the Licenses"). The Licenses are held by Mallinckrodt's U.S. subsidiary, Mallinckrodt Nuclear Medicine LLC, a Delaware limited liability company ("the Licensee"). Under the proposed transaction, Mallinckrodt will sell its interest in the Licensee to GLO Bidco US, LLC, a Delaware limited liability company ("the Buyer"), which is owned and controlled by investment funds managed by CapVest and its affiliates.[1] Attachment 1 provides the basis for this request. Attachment 2 presents a simplified pre- and post-transaction organizational chart.

Under the proposed transfer of control, the Licensee would remain the same, but would now be an indirect subsidiary of CapVest rather than Mallinckrodt. The proposed transfer of control does not involve any amendment to the Licenses and is not intended to result in any changes to the Licensee's name at this time, organization, NRC-licensed activities, or personnel responsible for such licensed activities. The Licensee intends to continue to have the same equipment, facilities, personnel and procedures needed to protect public health and safety, to conduct decommissioning activities, and to secure the licensed material.

Mallinckrodt is a global specialty pharmaceutical and nuclear imaging business that develops, manufactures, markets and distributes specialty pharmaceutical and biopharmaceutical products and nuclear imaging agents. Mallinckrodt supports the diagnosis of disease with nuclear medicine imaging agents. The Licensee manufactures and distributes radiopharmaceutical

[1] CapVest manages the following investment funds: CapVest Equity Partners III, LP, CapVest Equity Partners III B, LP, CapVest Equity Partners III C, LP and affiliated funds (the "Funds").

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products to healthcare customers throughout the United States from its Maryland Heights, Missouri, facility.

CapVest is a private equity firm situated in the United Kingdom with a portfolio of investments across a number of sectors. Among other things, CapVest manages the Funds which serve as the controlling investors of the IBA Molecular group of companies (the "IBAM Companies"), a leading developer, manufacturer, and distributor of radiopharmaceutical products with operations throughout Europe and Asia. The IBAM Companies hold a number of licenses issued by the French Nuclear Safety Authority ("ANS") to distribute, possess, use, import, export, and manufacture radionuclides in sealed and unsealed sources. ANS is the authority tasked with regulating nuclear safety and radiation protection in France. CapVest is also a regulated entity in the United Kingdom under the United Kingdom's Financial Conduct Authority, which is similar in function to the U.S. Securities and Exchange Commission.[2]

The parties executed a stock purchase agreement on August 24, 2016, and the transaction will likely close in the first half of 2017, subject to the receipt of all necessary regulatory approvals. The parties are also seeking review of the transaction by the Committee on Foreign Investment in the United States ("CFIUS"). The parties respectfully request the NRC's review and written approval of this application by no later than December 1, 2016. We also respectfully request that the NRC's approval of the transfer of the Licenses apply for one year, to accommodate any unanticipated delays in closing the transaction as a result of the timing of the parties receiving other regulatory approvals.

If you have any questions or comments pertaining to this transaction or CapVest, please contact CapVest's counsel for nuclear regulatory matters, Amy Roma, at Hogan Lovells US LLP (202-637-6831/amy.roma@hoganlovells.com). If you have any questions about the Licenses or Mallinckrodt, please contact Eric Berry, Vice President—Environmental Law, at Mallinckrodt Nuclear Medicine LLC (314-654-6878/Eric.Berry@mallinckrodt.com).

Enclosures: Attachment 1, Application for Approval of Transfer of Control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD

Attachment 2, Simplified Organizational Chart Describing the Transaction

cc: Bryan Parker, USNRC Region III
Manuel Diaz, Radiation Safety Officer, Mallinckrodt Nuclear Medicine LLC
Amy Roma, Hogan Lovells US LLP
Steven Poplawski, Bryan Cave LLP
Eric Berry, Mallinckrodt Pharmaceuticals

[2] CapVest's registration with the United Kingdom's Financial Conduct Authority can be accessed at the following link: https://register.fca.org.uk/shpo_searchresultspage?search=CapVest+partners+llp&TOKEN=5zq3mgf0d8qk.

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in the Application for Approval of Transfer of Control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD pertaining to Mallinckrodt plc and its companies is true and correct.

Executed on September 1, 2016.

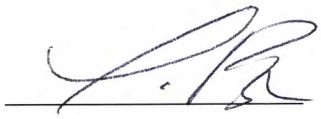
by KRW

LEGAL APPROVED JEB

Kathy Schaefer
Vice President, Finance, and Corporate Controller
Mallinckrodt plc
675 McDonnell Blvd.
Hazelwood, MO 63042

I declare under penalty of perjury under the laws of the United States of America that to the best of my knowledge the information contained in the Application for Approval of Transfer of Control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD pertaining to CapVest Partners LLP and its companies is true and correct.

Executed on August 30th, 2016.



Tina Page
Designated Member
CapVest Partners LLP
100 Pall Mall
London SW1Y 5NQ

Attachment 1

Application for Approval of Transfer of Control of NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD

This information is submitted consistent with NUREG-1556, Vol. 15, Rev. 1, *Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses,* at Sections 5.1 through 5.6.

SECTION 5.1. DESCRIPTION OF TRANSACTION

1. *A complete clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and changes of ownership.*

Mallinckrodt Nuclear Medicine LLC ("the Licensee") holds NRC Material License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD ("the Licenses"). The Licensee is an indirect subsidiary of Mallinckrodt plc ("Mallinckrodt"), an Irish corporation with its U.S. headquarters in St. Louis, Missouri. Under a share purchase agreement executed on August 24, 2016, Mallinckrodt, through certain subsidiaries, [3] intends to sell the Licensee to GLO Bidco US, LLC, a Delaware limited liability company ("the Buyer"), and an indirect subsidiary of investment funds managed by CapVest Partners LLP,[4] a United Kingdom partnership ("CapVest"), and its affiliates. The Buyer was formed specifically to effectuate the share purchase of the Licensee from Mallinckrodt. Attachment 2 presents a simplified pre- and post-transaction organizational chart.

Under the proposed transfer of control, the Licensee would remain the same, but would now be an indirect subsidiary of CapVest. The proposed transfer of control does not involve any amendment to the Licenses and is not intended to result in any changes to the Licensee's name at this time, organization, NRC-licensed activities, or personnel responsible for such licensed activities. The Licensee intends to continue to have the same equipment, facilities, personnel and procedures needed to protect public health and safety, to conduct decommissioning activities, and to secure the licensed material. Financial assurance for decommissioning is addressed in section 5.5 below.

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[3] Specifically, these wholly-owned subsidiaries are Mallinckrodt Chemical Holdings (UK) Limited and Mallinckrodt Netherlands Holdings B.V., a Netherlands company. Mallinckrodt in the same transaction will also sell Mallinckrodt Netherlands Holdings B.V. to a newly formed indirect subsidiary of the Funds managed by CapVest, GLO Dutch Bidco B.V. GLO Dutch Bidco B.V. is the direct parent company of the Buyer, and post-transaction will become an indirect parent company of the Licensee and Mallinckrodt Netherlands Holdings B.V. Thus, Mallinckrodt Netherlands Holdings B.V. will become a sister company (instead of a parent company) of the Licensee. GLO Dutch Bidco B.V. is an indirect subsidiary of GLO HoldCo S.C.A. (Luxemburg). At closing, the investment funds managed by CapVest (defined in footnote 4) will hold a 62.3% interest in GLO HoldCo S.C.A., and the remaining minority equity ownership interest will be held by managers (2.5%), and by co-investors comprised of funds managed or advised or operated by (i) GSO Capital Partners or their affiliates; and (ii) Northwestern Mutual Life Insurance Company or their affiliates (35.2%). *See* Attachment 2.

[4] CapVest manages the following investment funds: CapVest Equity Partners III, LP, CapVest Equity Partners III B, LP, CapVest Equity Partners III C, LP and affiliated funds (the "Funds").

2. *The new name of the licensed organization. If there is no change, the licensee should so state.*

There will be no change in the name of the Licensee in connection with the proposed transaction.

3. *The new licensee contact and telephone number(s) to facilitate communications.*

The Licensee contact and telephone information will remain the same. The contact information for the Licensee's Radiation Safety Officer is below:

Mr. Manuel Diaz
Radiation Safety Officer
Mallinckrodt Nuclear Medicine LLC
2703 Wagner Place
Maryland Heights, MO 63043
Telephone: (314) 654-7661

SECTION 5.2. CHANGES OF PERSONNEL

1. *Any changes in personnel having control over licensed activities (e.g., officers of a corporation and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license applications as responsible for radiation safety or use of licensed material). The licensee should include information concerning the qualifications, training and responsibilities of new individuals.*

There are no planned changes in personnel having control over licensed activities.

SECTION 5.3. CHANGES OF LOCATION, EQUIPMENT & PROCEDURES

1. *A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).*

No such changes are planned.

2. *A detailed description of any changes in the use, possession, location or storage of the licensed materials.*

No such changes are planned.

3. *Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.*

No such changes are planned.

SECTION 5.4. SURVEILLANCE RECORDS

1. *An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. A description of the status of all surveillance requirements and records should also be provided.*

Such records will remain with the Licensee and are current and will be current at the time of the transfer.

SECTION 5.5 DECOMMISSIONING AND RELATED RECORDS TRANSFERS

1. *Confirmation that all records concerning the safe and effective decommissioning/closure of the facility; public dose and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee if licensed activities will continue at the same location.*

Such records will remain with the Licensee.

2. *A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, is the transferee knowledgeable of the extent and levels of contamination and applicable decommissioning requirements, and does the transferee agree to assume full liability for the decontamination of the facility or site?*

The status of the Licensee's U.S. facility will remain unchanged. The liability for any decommissioning or decontamination will remain with the Licensee. The transferee is knowledgeable of the extent and levels of contamination and applicable decommissioning requirements of the Licensee and shall address the financial assurance with regard to those decommissioning obligations as set forth in the response to item 5.5.3 below.

3. *A description of any decontamination plans, including financial surety arrangements of the transferee. This should include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.*

The Licensee currently maintains two NRC-approved surety bonds to provide financial assurance for decommissioning for NRC Material License Nos. 24-04206-01 and 24-04206-02. On August 16, 2016, the NRC approved an update provided by the Licensee to its decommissioning cost estimate, which enabled the Licensee to seek NRC approval to lower the amount of the surety bonds. On August 26, 2016, the Licensee submitted an updated financial assurance package to the NRC, which included revised surety bonds to align with the lower decommissioning cost

estimate approved by the NRC on August 16, 2016, as well as to make other conforming changes, such as revising the name of the licensee to reflect a recent name change on the license to "Mallinckrodt Nuclear Medicine LLC." Therefore, separate and apart from this transaction, the Licensee has submitted the documentation to the NRC that is necessary to lower the amount of the surety bonds consistent with the NRC's August 16 approval of a lower decommissioning cost estimate.

CapVest is also presently evaluating with the Licensee whether to ultimately replace the surety bonds with another NRC-approved financial assurance instrument at closing. Should this option be pursued, the parties will submit a request to the NRC for approval of the new proposed financial assurance documents in accordance with the NRC's guidance set forth in NUREG-1757, Vol. 3, Rev. 1, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness."

The Licensee's decommissioning plans will remain unchanged as a result of the planned transaction, and the liability for any decommissioning or decontamination will remain with the Licensee "as is" consistent with the current decommissioning plan.

SECTION 5.6. TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

Confirmation that the transferee agrees to abide by all commitments and representations previously made by the transferor. These include, but are not limited to: maintaining decommissioning records; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.

With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before the change of control or ownership.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee proposes alternative measures for meeting the requirements; or the transferor provides a commitment to close out all such actions with NRC before license transfer.

The change in control resulting from the proposed transaction would not create a new licensee. The Licensee will continue to abide by the requirements in the Licenses and NRC regulations. There are no open inspection items pertaining to the Licenses.

1. *Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of*

the transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

All the parties referenced herein have agreed to the change in control over the Licensee. There are no open inspection items pertaining to the Licenses.

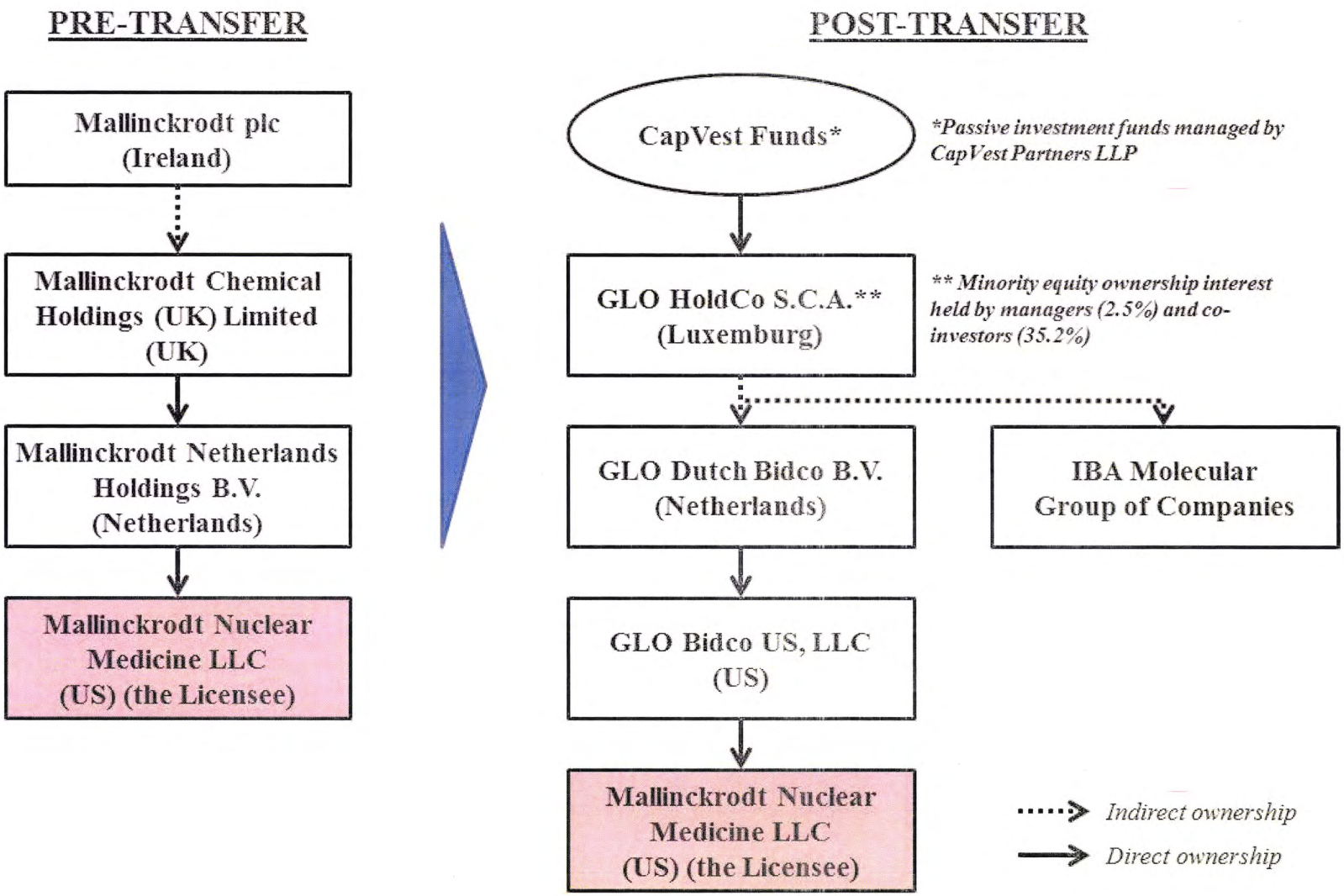
2. *A commitment by the transferee to abide by all constraints, conditions, requirements, representations, commitments identified in the existing licenses. If not, the transferee must provide a description of its program to ensure compliance with the license and regulations.*

The change in control resulting from the transaction would not create a new licensee and would not change the Licensee's existing commitments under the Licenses and NRC regulations. Following the transaction, the Licensee agrees to continue to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing Licenses.

Attachment 2

Pre- and Post-Transaction Simplified Organizational Chart

Pre- and Post-Transaction Simplified Organizational Chart



FOLD on this line and place in shipping pouch with **bar code and delivery address** visible

1. Fold the first printed page in half and use as the shipping label.
2. Place the label in a waybill pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.
3. Keep the second page as a receipt for your records. The receipt contains the terms and conditions of shipping and information useful for tracking your package.

.egal Terms and Conditions

Tendering packages by using this system constitutes your agreement to the service conditions for the transportation of your shipments as found in the applicable FedEx Service Guide, available upon request. FedEx will not be responsible for any claim in excess of the applicable declared value, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the applicable FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of 100 USD or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is 500 USD, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see applicable FedEx Service Guide. FedEx will not be liable for loss or damage to prohibited items in any event or for your acts or omissions, including, without limitation, improper or insufficient packaging, securing, marking or addressing, or the acts or omissions of the recipient or anyone else with an interest in the package. See the applicable FedEx Service Guide for complete terms and conditions. To obtain information regarding how to file a claim or to obtain a Service Guide, please call 1-800-GO-FEDEX (1-800-463-3339).