

February 4, 2016

Ms. Karen Burke, Director
Environmental Remediation
Mallinckrodt Pharmaceuticals
675 McDonnell Boulevard
St. Louis, MO 63042

SUBJECT: ISSUANCE OF MALLINCKRODT AMENDMENT NO. 7 APPROVING
THE MALLINCKRODT FEBRUARY 12, 2015, LICENSE AMENDMENT
REQUEST (DOCKET NO. 40-6563)

Dear Ms. Burke:

By letter dated February 12, 2015, the U.S. Nuclear Regulatory Commission (NRC) received a license amendment application from Mallinckrodt, LLC. (Mallinckrodt) to amend NRC Source Materials License No. STB-401 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15063A404). In this request, Mallinckrodt requests the option to perform direct dose assessment of residual radioactivity in addition to using Derived Concentration Guideline Levels (DCGLs) to demonstrate compliance with the license termination criteria in 10 CFR 20.1402 at the Mallinckrodt site in St. Louis, Missouri. The decommissioning plan that was previously approved for Mallinckrodt only included the use of the DCGL approach to demonstrate compliance with the license termination criteria.

The NRC is hereby approving your February 12, 2015, request by issuing License Amendment No. 7. By this letter, the NRC is informing you that Mallinckrodt is now permitted to demonstrate compliance with license termination criteria in 10 CFR 20.1402 either by using the previously approved DCGL values or by performing a direct dose assessment of residual radioactivity.

License Amendment No. 7 adds License Condition 21 as follows:

21. The licensee shall demonstrate compliance with the license termination criteria in 10 CFR 20.1402 in accordance with either the Mallinckrodt C-T Decommissioning Project, C-T Phase II Decommissioning Plan, Revision 2, submitted to NRC on October 14, 2008, and revisions submitted on June 3, 2010, or by performing a direct dose assessment of residual radioactivity as described in the Mallinckrodt License Amendment Request dated February 12, 2015.

The bases for the addition of License Condition 21, and the NRC's approval of Mallinckrodt's license amendment request, are described in the enclosed Safety Evaluation Report (SER). Associated with the enclosed SER, the staff evaluated the environmental impacts of approving the license amendment request. The staff has determined that approving the license

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amendment request would not result in any significant environmental impacts. A notice of availability of an Environmental Assessment (EA) and a Finding of No Significant Impact were prepared and published in the *Federal Register* (ADAMS Accession No. ML15275A181). The EA was transmitted to you by letter dated January 28, 2016 (ADAMS Accession No. ML15268A294).

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any further questions, please contact Karen Pinkston at (301) 415-3650 or via email at Karen.Pinkston@nrc.gov.

Sincerely,

/RA/

John R. Tappert, Director
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 040-6563
License No.: STB-401

Enclosures:

1. License Amendment Request SER
2. Mallinckrodt Amendment No. 7

cc: Mallinckrodt, LLC. Distribution List

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Docket No.: 040-6563
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ADAMS Accession No.: ML15286A178

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