

January 28, 2016

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

SUBJECT: ENVIRONMENTAL ASSESSMENT ASSOCIATED WITH 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 Document 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 has completed its review of the request and will be issuing a Safety Evaluation Report (SER) regarding the license amendment request. Associated with the SER, the staff evaluated the environmental impacts of approving the license amendment request. The staff has determined that, should the license amendment request be approved, significant environmental impacts would not result. For this action, a Notice of Availability Environmental Assessment and Finding of No Significant Impact was prepared and published in the *Federal Register*. By this letter we are transmitting to you a copy of the Environmental Assessment.

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>.

K. Burke

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

Sincerely,

/RA/

Karen Pinkston, Systems Performance Analyst
Performance Assessment Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 40-6563
License No.: STB-401

Enclosure:
Environmental Assessment

cc: Mallinckrodt Distribution List

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