



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 12, 2021

James A. Zelinsky, Director
Division of Safety and Logistics
CFSAN Office of Management
Department of Health and Human Services
Food and Drug Administration
Harvey W. Wiley Building HFS-657
5001 Campus Drive
College Park, MD 20740

**SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
ADMINISTRATION, LICENSE AMENDMENT, MAIL CONTROL NO. 624491**

Dear Mr. Zelinsky:

This refers to your license amendment request dated December 17, 2020, with the "Report of Radiological Survey" dated December 2020. Please find enclosed Amendment No. 17 removing the Harvey W. Wiley Building as an authorized location of use in accordance with the requirements of the applicable NRC Termination Rule in 10 CFR 30.36. All facilities in this building previously used for licensed activities may be released for unrestricted. We understand that licensed activities will continue at the Muirkirk road Complex.

An environmental assessment for this action was not required, since this action is categorically excluded under 10 CFR 51.22(c)(20).

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please contact me at (610) 337-5040 or by electronic mail to Elizabeth.ullrich@nrc.gov so that appropriate corrections or answers can be provided.

You will be periodically inspected by the NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action(s) against you. This could include issuance of a Notice of Violation, or Imposition of a Civil Penalty, or an Order Suspending, Modifying or Revoking Your License as specified in the NRC Enforcement Policy. The NRC Enforcement Policy is available at: <http://www.nrc.gov/reading-rm/doc-collections/enforcement/>.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety
Region I

Docket No. 030-36120
License No. 19-30771-01
Mail Control No. 624491

Enclosure:
Amendment No. 17

cc: Charles Watts, Radiation Safety Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG
ADMINISTRATION, LICENSE AMENDMENT, MAIL CONTROL NO. 624491 DATED MARCH
12, 2021

DOCUMENT NAME: [G:\WBL Documents\WBL License Cover Letter\L19-30771-01.624491.docx
SUNSI Review Complete: Betsy Ullrich

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NAME	Betsy Ullrich							
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