UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 13, 2018

Brian Baker
Center Director
U.S. Food and Drug Administration
Winchester Engineering & Analytical Center
109 Holton Street
Winchester, MA 01890

SUBJECT: THE WINCHESTER ENGINEERING AND ANALYTICAL CENTER– REQUEST FOR APPROVAL OF DECOMMISSIONING PLAN

Dear Mr. Baker:

By letter dated July 21, 2017, the Food and Drug Administration (FDA), submitted a Decommissioning plan (DP), Environmental Report, and Statement of Intent (Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML17215A951) to the U.S. Nuclear Regulatory Commission (NRC) for the Winchester Engineering and Analytical Center (WEAC) located at 109 Holton Street, Winchester, Massachusetts.

In 2016, when FDA started to plan for the construction of a new laboratory on the site, FDA sought the services of an independent contractor to survey the surface and subsurface soils in the area. In November 2016, a preliminary survey of soils in the expected excavation area revealed Uranium-238 and Radium-226 (preliminary data indicates they are in equilibrium) at concentrations greater than three times the screening values (above background) listed in NUREG 1757, “Consolidated Decommissioning Guidance: Decommissioning Process for Materials Licensees,” Vol 2, Revision 1. FDA then sought guidance from the NRC with respect to remediating and releasing the site for unrestricted use (ADAMS Accession No. ML16347A523). In the July 21, 2017 letter, the FDA proposed a partial site release of soil areas at the WEAC to enable the construction of new buildings on the site in the future.

History:

In 1952, the Atomic Energy Commission (AEC) constructed the WEAC site to continue development of methods for extraction of uranium and thorium from ore and to prepare metal-grade uranium tetrafluoride. According to a Department of Energy (DOE) Report on the WEAC site, a few wheelbarrow loads of pitchblende residues were buried at the rear of the laboratory building and covered with soil and grass sometime between 1952 and 1959 (ADAMS Accession No. ML18215A057). Beginning in 1959, however, the work at WEAC shifted to laboratory testing of environmental analysis methods pertaining to uranium waste. In 1961, this work was discontinued and the facility was transferred to the Department of Health, Education and

Welfare (HEW), the predecessor to the Department of Health and Human Services of which the FDA is part. The HEW used the site as a low-level environmental radiation surveillance laboratory. Prior to HEW taking over the site in 1961, the HEW Winchester Bureau of Radiological Health performed a radiological survey of the facility. During the survey, the only radioactivity found was limited to certain lab hoods.

Thereafter, at the request of the DOE's predecessor, the Energy Research and Development Administration, Oak Ridge National Laboratory (ORNL) conducted a preliminary radiological survey of the site on January 25, 1977. In its report dated March 1980, ORNL concluded that no personnel safety problems or limitations for current operation existed and that further radiation surveys were not warranted. Based in part on the 1977 survey performed by ORNL, the DOE concluded that there was no residual radioactivity in excess of DOE guidelines at the site resulting from past AEC activities. As a result of this conclusion and because the facility was licensed by the NRC to possess and use radioactive materials, the DOE eliminated the site from consideration for inclusion in the Formerly Utilized Sites Remedial Action Program (FUSRAP) (ADAMS Accession Nos. ML18215A059, ML18215A057)

Discussion:

Over the past year, NRC has been reviewing the proposed DP along with the calculated Derived Concentration Guideline Levels (DCGLs) and preliminary characterization of the site. In addition, NRC has been evaluating the appropriate regulatory process to address the identified contamination, which is likely from past AEC activities. The exact levels of soil contamination caused by the legacy materials were unknown prior to the surveys performed in 2016. The FDA has since proceeded with its remediation of the area to meet the unrestricted release criteria of 10 CFR § 20.1402 in accordance with its DP. The final status surveys, dated August 16, 2018, appear to indicate that the contamination levels have been reduced below the calculated DCGLs (ADAMS Accession No. ML18232A458). Preliminarily, while the adequacy is still under review, the analyses, remediation, and surveys submitted to the NRC appear to have been performed consistent with NRC guidance for decommissioning found in NUREG 1757, Vol. 2, Revision 1.

Because the FDA plans to continue licensed activities in the area it sought to be partially released, the NRC staff has determined it would not be an efficient use of resources to release the area from FDA's license. Nonetheless, recognizing the FDA's efforts to remediate the contamination and in the interest of public health and safety, as part of our oversight function, the NRC staff will arrange for an independent confirmatory survey to confirm that the DCGLS meet the current radiological criteria for unrestricted use of a site under the 10 CFR § 20.1402. Upon satisfactory completion of this independent radiological survey, we will provide a letter stating whether the area meets the requirements of 10 CFR § 20.1402. The NRC staff does not plan to amend the FDA's license to release the area for unrestricted use given the FDA's plans to continue licensed activities in the subject area. Accordingly, the NRC staff recommends that upon receipt of this confirmatory letter, the FDA withdraw its license amendment request for a partial site release.

Because the new building area will not be released from the FDA's license, the FDA's Radiation Protection Program (RPP) obligations under 10 CFR § 20.1101 still apply to that area. To the extent changes to the RPP are necessary to account for construction activities in the new building area, License Condition 21 permits the FDA to change its RPP in certain circumstances without NRC approval.

Additionally, we recommend that the FDA continue to work with the United States Army Corps of Engineers responsible for the FUSRAP program to determine whether additional FUSRAP material exists on the site or on the adjacent properties.

Should you have any questions concerning this request for additional information, please contact James Smith, Project Manager at 301-415-6103 or the undersigned at 301-415-6631.

Sincerely,

/RA/

Stephen Koenick, Chief
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 030-04675
License No.: 20-08361-01
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Cc: Elon Malkin, FDA/WEAC

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ADAMS Accession No.: ML18215A047

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