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

July 31, 2019

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 – LETTER INDICATING THAT SURVEY UNITS 4.1 AND 4.2 MEET THE REQUIREMENTS OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*, 20.1402 FOR UNRESTRICTED RELEASE

Dear Mr. Baker:

This letter is to inform you that the U.S. Nuclear Regulatory Commission (NRC) has completed its review of the Winchester Engineering and Analytical Center (WEAC) final status survey reports of survey units 4.1 and 4.2 and has reasonable confidence that these survey units meet the requirements of Title 10 of the C*ode of Federal Regulations* (10 CFR) 20.1402 for unrestricted use. As you may recall, by letter dated March 20, 2019 (Agencywide Documents Access and Management System [ADAMS] Accession Number ML19073A063), the NRC staff previously informed the Food and Drug Administration (FDA) that it had reasonable confidence that the portion of the site, identified as survey units 1, 2, and 3, met the requirements of 10 CFR 20.1402 for unrestricted use. The status of survey unit 4, which was included in the FDA request, was not addressed by the NRC staff because an anomaly was identified during NRC sponsored confirmatory surveys. It was the NRC staff's understanding that the anomaly was not located in a generally accessed area and that proposed construction activities at the site would not disturb the area. Also, the FDA indicated it would address the suspect area in the future.

Subsequently, by email dated June 28, 2019 (ADAMS Accession Number ML19179A165 [pkg]), the FDA notified the NRC that it had recharacterized and resurveyed survey unit 4 for the WEAC as an impacted area (i.e., Class 1) and subdivided it into two separate survey units identified as survey units 4.1 and 4.2. The email included final status survey reports needed for NRC's reevaluation of survey unit 4 (now identified as survey units 4.1 and 4.2).

The NRC staff reviewed the FDA's survey reports and considered the previously performed confirmatory survey of the subject areas (ADAMS Accession Number ML19074A146), which adequately confirmed the submitted reports even though it predates the submitted final status surveys. The NRC staff determined that the FDA survey reports appropriately addressed survey units 4.1 and 4.2 and provide reasonable confidence that the survey units meet the requirements of 10 CFR 20.1402 for unrestricted use.

Consistent with our previous communication, the NRC staff does not plan to amend the FDA's license to release the remediated areas for unrestricted use given the FDA's plan to continue

licensed activities in the subject area. Accordingly, the NRC staff recommend that, upon receipt of this confirmatory letter, the FDA withdraw its license amendment request for a partial site release.

The NRC staff continues to recommend that the FDA work with the U.S. Army Corps of Engineers, the federal agency responsible for the Formerly Utilized Sites Remedial Action Program (FUSRAP), to determine whether additional FUSRAP material exists on the site or on adjacent properties.

Should you have any questions concerning this issue, 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
Control No.: 592468

cc: E. Malkin, FDA/WEAC

SUBJECT: THE WINCHESTER ENGINEERING AND ANALYTICAL CENTER – LETTER INDICATING THAT REMEDIATED AREAS MEET THE REQUIREMENTS OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*, 20.1402 FOR UNRESTRICTED RELEASE DATE**: July 31, 2019**

DISTRIBUTION:
ASchwartzman, NMSS GChapman, NMSS MRoberts, RI SHamman, RI
SAchten, NMSS

ADAMS Accession No.: ML19196A212 ***via e-mail**

OFFICE	DUWP	DUWP	DUWP	DUWP
NAME	JASmith	GChapman*	ASchwartzman	CMckenney*
DATE	07/31/2019	07/20/2019	07/22/2019	07/20/2019
OFFICE	DUWP	OGC		
NAME	SKoenick	IIrvin*		
DATE	07/20/2019	07/31/2019		

OFFICIAL RECORD COPY