MEMORANDUM

TO:	Janssen COVID-19 Vaccine EUA 27205
FROM:	Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research (CBER)
CC:	CBER Office of Vaccines Research and Review (OVRR) and CBER Office of Compliance and Biologics Quality (OCBQ)
DATE:	September 14, 2021
RE:	Addendum #5 (for Area 2, batches GMP14 and GMP17) to the June 11, 2021 memorandum entitled "Assessment of Certain Janssen COVID-19 Vaccine Batches"

The purpose of this addendum is to document the Agency's determination regarding the disposition of Janssen's AD26.COV2.S DS Area 2 batches 21003667 (GMP14) and 21004639 (GMP17) and/or vaccine manufactured from these batches.

I. Disposition of Janssen's AD26.COV2.S DS Batches GMP14 and GMP17

FDA has conducted a thorough review of available information concerning the manufacturing conditions of the EMOB facility during the time period in which Janssen's AD26.COV2.S DS batches GMP14 and GMP17 were made and the testing of the batches produced.[1] Based on the conditions present in the EMOB facility at the time batches GMP14 and GMP17 was manufactured, FDA has determined that the EMOB facility was not operating in full compliance with cGMP requirements at the time of manufacture. However, the quality of the product produced, as illustrated by a review of facility records and the results of the in process and release testing, support FDA's determination that DS batches GMP14 and GMP17 and/or vaccine manufactured from these batches are suitable for use.

The Agency reviewed, among other things, information provided to FDA and collected during FDA's inspections of the EMOB facility. This included information regarding manufacturing operations and waste flow procedures in place during the manufacture of Janssen DS batches

[1] See FDA's review entitled "CBER assessment of the quality of JNJ Ad26.COV2.S DS batches GMP14 and GMP17 (Area 2) manufactured at the EMOB facility," dated September 10, 2021.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

GMP14 and GMP17, and deviations associated with DS batches GMP14 and GMP17. Additionally, the Agency reviewed the in process and release testing results for DS batches GMP14 and GMP17. Based on its review of this information, the Agency concluded that the test results for DS batches GMP14 and GMP17 were within the defined quality specifications for these batches, which include tests for bioburden and endotoxin. Also, DS batches GMP14 and GMP17 were manufactured in the EMOB facility during a time period when mitigating measures had been implemented by Emergent to address the causes of the batch GMP8 contamination event. These mitigation measures included adjustments to waste flow, changes in personnel movement, and the segregation of personnel functions. That is, the media for DS batches GMP14 and GMP17 were prepared after these corrective actions had been implemented.

Given all the above, FDA has determined that DS batches GMP14 and GMP17 are suitable for use, considering the current COVID-19 public health emergency, and that the batches meet the EUA standard and will be added to the Janssen COVID-19 Vaccine EUA 27205 for distribution in the United States and for potential export to other countries.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov