

## 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 (OVR) and CBER Office of Compliance and Biologics Quality (OCBQ)

DATE: September 28, 2021

RE: Addendum #6 (for Area 1, batch GMP5) to the June 11, 2021 memorandum entitled “Assessment of Certain Janssen COVID-19 Vaccine Batches”

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The purpose of this addendum is to document the Agency’s determination regarding the disposition of Janssen’s AD26.COV2.S DS Area 1 batch 21004660 (GMP5)<sup>1</sup> and/or vaccine manufactured from this batch.

### I. Disposition of Janssen’s AD26.COV2.S DS Batch GMP5

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 batch GMP5 was made and the testing of the batch produced.<sup>2</sup> Based on the conditions present in the EMOB facility at the time batch GMP5 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 batch GMP5 and/or vaccine manufactured from this batch is 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

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<sup>1</sup> Batch GMP5 referred to in the June 11, 2021 memorandum, which failed to meet the Agency’s expectations for quality, was an entirely different batch manufactured in Area 2 of the EMOB facility with a different manufacturing date and batch number, and should not be confused with batch GMP5 here, which was manufactured in Area 1 of the EMOB facility.

<sup>2</sup> See FDA’s review entitled “CBER assessment of the quality of JNJ Ad26.COV2.S DS batch GMP5 (Area 1) manufactured at the EMOB facility,” dated September 24, 2021.

operations and waste flow procedures in place during the manufacture of Janssen DS batch GMP5, and deviations associated with GMP5. Additionally, the Agency reviewed the in-process and release testing results for batch GMP5. Based on its review of this information, the Agency concluded that the test results for batch GMP5 were within the defined quality specifications for this batch, which include tests for bioburden and endotoxin. Also, GMP5 was 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 (including reduction of waste levels), changes in personnel movement, and the segregation of personnel functions. That is, the media for batch GMP5 was prepared after these corrective actions had been implemented.

Given all the above, FDA has determined that GMP5 is suitable for use, considering the current COVID-19 public health emergency, and that it meets 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.