

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: June 15, 2021

RE: Addendum #1 (for Area 2, batch GMP10) 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.COVS.S DS Area 2 batch 21004264 (GMP10) and/or vaccine manufactured from this batch.

I. Disposition of Janssen's AD26.COVS.S DS Batch GMP10

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.COVS.S DS batch GMP10 was made and the testing of the batch produced.¹ Based on the conditions present in the EMOB facility at the time batch GMP10 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 GMP10 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 operations and waste flow procedures in place for the manufacture of Janssen DS batch GMP8, which was found to be cross-contaminated with AZ's adenovirus vectored vaccine. Additionally, the Agency reviewed the in process and release testing results for batch GMP10.

¹ See FDA's review entitled "CBER assessment of the quality of JNJ Ad26.COVS.S DS batch GMP10 manufactured at the EMOB facility (Area 2)," dated June 15, 2021.

Based on its review of this information, the Agency concluded that the test results for batch GMP10 was within the defined quality specifications for this batch. Also, GMP10 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, changes in personnel movement, and the segregation of personnel functions. That is, the media for batch GMP10 was prepared after these corrective actions had been implemented.

Given all the above, FDA has determined that GMP10 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 potential export to other countries.² Additionally, the same conditions noted in the June 11, 2021 memorandum will apply to the export of GMP10 and/or vaccine manufactured from this batch.

² The Agency notes it is only authorizing batch GMP10 and/or vaccine manufactured from this batch and not a combination of other batches that include batches GMP 5 through 9 or any batches not authorized under the EUA.