U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27205

EUA AMENDMENT – CONCURRENCE

July 2, 2021

Janssen Biotech, Inc.
Attention: Ms. Ruta Walawalkar
920 Route 202
Raritan, NJ 08869

Dear Ms. Walawalkar,

Please refer to your Emergency Use Authorization (EUA) for emergency use of Janssen COVID 19 Vaccine, issued on June 10, 2021, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

In reference to our EUA Amendment Concurrence letter regarding batch 21004264 (GMP10) dated June 15, 2021, we note the following error:

> The first paragraph included the wrong EUA issuance date.

In addition, we have updated the letter to remove the following condition for export from the United States:

> Janssen and Emergent agree that the following unredacted documents may be shared, under an appropriate confidentiality agreement, with the regulatory authorities of the countries where the vaccine will be administered— the FDA Form 483 and establishment inspection report from the most recent inspection of the facility, the June 11, 2021 memo *Assessment of certain Janssen COVID-19 Vaccine Batches*, and the June 15, 2021 addendum to the that memo.

This replacement concurrence letter incorporates the correction of the error and removal of the condition for export. The effective date for the concurrence will remain June 15, 2021, the date of the previous EUA Amendment Concurrence letter. Below is the substance of the reissued concurrence letter.

Please refer to your Emergency Use Authorization (EUA) for emergency use of Janssen COVID 19 Vaccine, issued on June 10, 2021, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We also refer you to your EUA amendments:

> submitted and received on March 5, 2021
> submitted and received on March 12, 2021
> submitted and received on March 17, 2021
> submitted and received on March 29, 2021

submitted and received on April 1, 2021
submitted and received on April 5, 2021
submitted and received on April 12, 2021
submitted and received on April 14, 2021
submitted and received on April 22, 2021
submitted and received on April 23, 2021
submitted and received on May 17, 2021

Based on our review of the available data and information, we have determined that Janssen's AD26.COV2.S DS Area 2 batch 21004264 (GMP10) is suitable for use and meets the EUA standard, which is outlined in your Letter of Authorization. Thus, we concur with your request to add this batch to the EUA. Because the Bayview facility was not operating in compliance with Current Good Manufacturing Practice requirements at the time this batch was manufactured, through this concurrence letter I am waiving Current Good Manufacturing Practice requirements for this batch, and only this batch, for the duration of this EUA. This concurrence does not add any other batches manufactured at this facility to the EUA at this time and does not add the facility itself to the EUA at this time, nor does the EUA cover vaccine manufactured by combining this batch with different batches of drug substance that are not authorized explicitly under this EUA.

We remind you that any changes that you plan to implement to the description of the product, manufacturing process, facilities, or equipment will need to be submitted as an amendment to the EUA and not implemented without concurrence by the Agency.

If you have any questions, please contact the Regulatory Project Manager, Sudhakar Agnihothram, PhD at 202-870-6949.

Sincerely,

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Marion Gruber, PhD
Director
Office of Vaccines and Research
Center for Biologics Evaluation and Research