U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27205

EUA AMENDMENT – CONCURRENCE
November 05, 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, re-issued on October 20, 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 29, 2021
submitted and received on April 12, 2021
submitted and received on August 13, 2021
submitted and received on August 27, 2021
submitted and received on September 10, 2021
submitted and received on September 28, 2021
submitted and received on October 28, 2021

Based on our review of the available data and information, we have determined that the Janssen's AD26.COV2.S DS Area 1 batches 21004663 (GMP 6) and 21004329 (GMP 4) are suitable for use and meet the EUA standard, which is outlined in your Letter of Authorization. Thus, we concur with your request to add these batches to the EUA. Because the Bayview facility was not operating in compliance with Current Good Manufacturing Practice requirements at the time these batches were manufactured, through this concurrence letter, I am waiving Current Good Manufacturing Practice requirements for these batches, and only these batches, 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 these batches 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,

--/S/--

Peter Marks, MD, PhD
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research