U.S. FOOD & DRUG ADMINISTRATION

Our Reference: EUA 27205

Amended Emergency Use Authorization – Concurrence
APRIL 07, 2022

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 November 19, 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 February 18, 2022 (EUA 27205/275)
- submitted and received on March 4, 2022 (EUA 27205/281)
- submitted and received on March 8, 2022 (EUA 27205/284)

In summary, your amendments describe the following Chemistry, Manufacturing and Control changes:

i) Information and data to support the extension of the shelf-life of Janssen COVID-19 Vaccine stored at 2-8°C, from 9 months to 11 months.

We have completed our review and, based on the information submitted, we concur with these changes. Please note that the shelf-life extension applies to all batches that have been released to the US market. 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,

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