

Our Reference: EUA 27205

**Amended Emergency Use Authorization – Concurrence**  
MARCH 04, 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)

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 6 months to 9 months.
- ii) Information and data to revise the following specifications for Janssen COVID-19 Vaccine Drug Substance
  - Infectious Units specification for release and stability
  - Ratio Virus Particles/Infectious Units Specification for release and stability
- iii) Information and data to revise the following specifications for Janssen COVID-19 Vaccine Drug Product
  - Infectious Units specification for release
  - Ratio Virus Particles/Infectious Units Specification for release

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