Our Reference: EUA 27205

EUA AMENDMENT – CONCURRENCE
June 10, 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 February 27, 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 amendment submitted and received on June 09, 2021 (EUA 27205/116).

In summary, your amendment provides information and data to support the extension of the shelf-life of Janssen COVID-19 Vaccine stored at 2-8^{o}C, from 3 months to 4.5 months.

We have completed our review and based on the information submitted, we concur with this change. 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,

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