DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

January 31, 2022

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

Re: EUA 27205 - Emergency Use Authorization of Janssen COVID-19 Vaccine, Reissued on November 19, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3)
January 31, 2022 Submission to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) – (including Full EUA Prescribing Information) and the Fact Sheet for Recipients and Caregivers.

Dear Ms. Walawalkar:

This letter is to notify you that we have granted the following changes to your authorized Fact Sheets as requested by the Food and Drug Administration (FDA).

The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) is revised to include the following new information about SPIKEVAX:

> **AVAILABLE ALTERNATIVES**
> COMIRNATY (COVID-19 Vaccine, mRNA) and SPIKEVAX (COVID-19 Vaccine, mRNA) are FDA-approved vaccines to prevent COVID-19 caused by SARS-CoV-2.

The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has also been updated to include other minor editorial changes.

In addition, the Fact Sheet for Recipients and Caregivers has been revised to include the following new information about SPIKEVAX:

> **ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?**
> Other choices for preventing COVID-19 are COMIRNATY and SPIKEVAX, which are FDA-approved COVID-19 vaccines.

By submitting these amendments for review and concurrence by the FDA, you have complied with the Conditions of Authorization stated in the November 19, 2021, letter re-authorizing the emergency use of Janssen COVID-19 Vaccine.

Sincerely,

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Peter W. Marks, M.D., Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research