DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

August 30, 2021

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 June 10, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3)
Multiple Amendments dated July 28, 2021 and August 27, 2021 to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Authorized Fact Sheet for Recipients and Caregivers.

Dear Ms. Walawalkar:

This letter is to notify you that we have reviewed your requested revisions to your Authorized EUA Fact Sheets, as well as FDA-required changes to include new information about syncope and the availability of an FDA approved vaccine to prevent COVID-19, and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Full Prescribing Information) to include the following new information.

5 WARNINGS AND PRECAUTIONS

'**5.4 Syncope**' Section was added and includes the following information:

"Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting."

6. OVERALL SAFETY SUMMARY

6.2 Post-Authorization Experience

Lymphadenopathy
Syncope, Paraesthesia, Hypoesthesia.
Ear and labyrinth disorders: Tinnitus.
Gastrointestinal disorders: Diarrhea, Vomiting.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency. In addition, the following Section was modified as follows:

AVAILABLE ALTERNATIVES

Comirnaty (COVID-19 Vaccine, mRNA) is an FDA-approved vaccine to prevent COVID-19 caused by SARS-CoV-2.

In addition, the EUA Fact Sheet for Recipients and Caregivers has been revised to remove from several sections the statement that there is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19 and to include the following new information:

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE JANSSEN COVID-19 VACCINE?

- have ever fainted in association with an injection.

WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?

- swollen lymph nodes.
- unusual feeling in the skin (such as tingling or a crawling feeling) (paresthesia), decreased feeling or sensitivity, especially in the skin (hypoesthesia).
- persistent ringing in the ears (tinnitus).
- diarrhea, vomiting.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES JANSSEN COVID-19 VACCINE?

Another choice for preventing COVID-19 is Comirnaty, an FDA-approved COVID-19 vaccine.

By submitting these amendments for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the June 10, 2021, letter re-authorizing the emergency use of Janssen COVID-19 Vaccine.

Sincerely,

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