DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

July 12, 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 May 21, 2021 – July 8, 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 changes and data to support revisions to your Authorized EUA Fact Sheets, as well as FDA-required changes to include new information about Guillain-Barré syndrome and that your request is granted.

We concur with the updates to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following new information, changes and clarifications:

5 WARNINGS AND PRECAUTIONS

- In **Section 5.2 Thrombosis with Thrombocytopenia:** The sentence **"**Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal." was deleted and replaced with "The reporting rate of thrombosis with thrombocytopenia following administration of the Janssen COVID-19 Vaccine has been highest in females ages 18 through 49 years; some have been fatal."
- Subsection **'5.3 Guillain-Barré Syndrome'** including the following information was added: Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination.

6 OVERALL SAFETY SUMMARY

- The sentence "Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, with thrombocytopenia have been reported following the Janssen COVID-19 vaccine." was deleted.
- The following was added to this section: "Severe allergic reactions (including anaphylaxis), thrombosis with thrombocytopenia, Guillain-Barré syndrome, and capillary leak syndrome

have been reported following administration of the Janssen COVID-19 Vaccine during mass vaccination outside of clinical trials."

6.2 Post Authorization Experience

- The sentence "Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, combined with thrombocytopenia" was deleted
- The following was added to this section: Because these reactions are reported voluntarily, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.
    - Blood and Lymphatic System Disorders: Thrombosis with thrombocytopenia
    - Immune System Disorders: Allergic reactions, including anaphylaxis
    - Nervous System Disorders: Guillain-Barré syndrome
    - Vascular Disorders: Capillary leak syndrome, Thrombosis with thrombocytopenia

19 HOW SUPLLIED/STORAGE AND HANDLING

- This section was updated to state that at room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw.

Minor editorial changes to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) were made for clarity and consistency. In addition, other changes consistent with those described above were made to the Short Version of the Fact Sheet.

In addition, the EUA Fact Sheet for Recipients and Caregivers has been updated to include the following new information and changes in the section "WHAT ARE THE RISKS OF THE JANSSEN COVID-19 VACCINE?":

- The sentence "Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine" was revised to "Blood clots involving blood vessels in the brain, lungs, abdomen, and legs along with low levels of platelets (blood cells that help your body stop bleeding), have occurred in some people who have received the Janssen COVID-19 Vaccine."
- The following sentence was deleted: "Most people who developed these blood clots and low levels of platelets were females ages 18 through 49 years." and replaced with: "Reporting of these blood clots and low levels of platelets has been highest in females ages 18 through 49 years."
- The following information was added under a new subsection entitled "Guillain Barré syndrome: Guillain Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) has occurred in some people who have received the Janssen COVID-19 Vaccine. In most of these people, symptoms began within 42 days following receipt of the Janssen COVID-19 Vaccine. The chance of having this occur is very low. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:
    - Weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body

- Difficulty walking
- Difficulty with facial movements, including speaking, chewing, or swallowing
- Double vision or inability to move eyes
- Difficulty with bladder control or bowel function"

In addition, minor editorial changes to the EUA Fact Sheet for Recipients and Caregivers were made for clarity.

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