DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD

January 11, 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)
November 24, 2021 and December 21, 2021 Submissions to Update the Authorized Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) – (including Full EUA Prescribing Information) and the Authorized 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 you and further revised by the Food and Drug Administration (FDA).

The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (Full Prescribing Information) is revised to include the following new information:

5 WARNINGS AND PRECAUTIONS

5.3 Immune Thrombocytopenia (ITP)

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of immune thrombocytopenia (ITP) during the 42 days following vaccination. Individuals with a history of ITP should discuss with their healthcare provider the risk of ITP and the potential need for platelet monitoring following vaccination with the Janssen COVID-19 Vaccine.

Related changes were also made to the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (short version) for consistency. The EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has also been updated to include other minor editorial changes.

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

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

An additional bullet was added under the heading: Tell the vaccination provider about all of your medical conditions, including if you:

- have ever had a low level of platelets (blood cells that help your body stop bleeding).

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

Immune Thrombocytopenia (ITP)

Immune Thrombocytopenia (ITP) is a disorder that can cause easy or excessive bruising and bleeding due to very low levels of platelets. ITP 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. If you have ever had a diagnosis of ITP, talk to your vaccination provider before you get the Janssen COVID-19 Vaccine. You should seek medical attention right away if you develop any of the following symptoms after receiving the Janssen COVID-19 Vaccine:

- Easy or excessive bruising or tiny blood spots under the skin beyond the site of the injection,
- Unusual or excessive bleeding.

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,

--/S/--

Peter Marks, MD, PhD
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research