



December 14, 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 November 19, 2021, Under Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3)
December 14, 2021 Submission 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 required 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:

4 CONTRAINDICATIONS

4.2 Thrombosis with Thrombocytopenia

Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (e.g. AstraZeneca's COVID-19 vaccine which is not authorized or approved in the United States) [*see Warnings and Precautions (5.2)*].

5 WARNINGS AND PRECAUTIONS

5.2 Thrombosis with Thrombocytopenia Syndrome (TTS)

This section was revised to state the following:

Reports to the Vaccine Adverse Events Reporting System (VAERS), a passive surveillance system, provide evidence for an increased risk of thrombosis with thrombocytopenia syndrome (TTS) with onset of symptoms approximately one to two weeks after administration of the Janssen COVID-19 Vaccine. An analysis of VAERS reports of TTS following the receipt of the Janssen COVID-19 Vaccine used the following case definition:

- a thrombosis in an unusual location for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) and new-onset

thrombocytopenia (i.e., platelet count <150,000/ μ L) occurring any time after vaccination;

or;

- new-onset thrombocytopenia (i.e., platelet count <150,000/ μ L), thrombosis in an extremity vein or pulmonary artery in the absence of thrombosis at an unusual location, and a positive anti-PF4 antibody ELISA test or functional HIT (heparin-induced thrombocytopenia) platelet test occurring any time after vaccination.

Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal.

Currently available evidence supports a causal relationship between TTS and the Janssen COVID-19 Vaccine.

6 OVERALL SAFETY SUMMARY

6.1 Clinical Trial Experience

Serious Adverse Events (SAEs) and other events of interest

This section was revised to state the following: However, post-authorization experience supports, a causal relationship with Janssen COVID-19 Vaccine for the event of transverse sinus thrombosis with thrombocytopenia [*see Warnings and Precautions (5.2) and Overall Safety Summary (6.2)*].

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:

WHO SHOULD NOT GET THE JANSSEN COVID-19 VACCINE?

You should not get the Janssen COVID-19 Vaccine if you:

- had a blood clot along with a low level of platelets (blood cells that help your body stop bleeding) following the Janssen COVID-19 Vaccine or following AstraZeneca's COVID-19 vaccine (not authorized or approved in the United States).

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

Blood Clots with Low Levels of Platelets

Blood clots with low levels of platelets following the Janssen COVID-19 Vaccine have been reported in males and females, across a wide age range of individuals 18 years and older; reporting has been highest in females ages 30 through 49 years (about 1 case for every 100,000 vaccine doses administered), and about 1 out of every 7 cases has been fatal.

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