U.S. FOOD & DRUG ADMINISTRATION

Review Memorandum

Date:	**June 1, 2023**
To:	**The File**
From:	**Sudhakar Agnihothram, PhD (DVRPA/OVRR)**
Through:	**David C. Kaslow, MD (OVRR)**
Sponsor name:	**Janssen Biotech, Inc.**
Application Number:	**EUA 27205**
Product:	**Janssen COVID-19 Vaccine**
Subject:	**Memorandum supporting revocation of Janssen's EUA 27205**

I. Background

On May 22, 2023, Janssen BioNTech, Inc. (Janssen) submitted a request for voluntary withdrawal of the EUA for Janssen COVID-19 Vaccine, issued on February 27, 2021, and subsequently amended. Janssen stated the following as the basis for their withdrawal request:

- the last lots of the Janssen COVID-19 Vaccine purchased by the United States Government have expired
- there is no demand for new lots of the Janssen COVID-19 Vaccine in the United States
- Janssen does not intend to update the composition of this vaccine[1]
- availability of other safe and effective COVID-19 vaccines in the U.S.

II. Basis for Revocation

Based on Janssen's request, FDA understands that Janssen no longer intends to offer the vaccine in the United States or manufacture any lots of Janssen COVID-19 Vaccine for distribution in the United States under the EUA 27205. The authorization of a biological product for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when circumstances make such

[1] Based on communications with Janssen, FDA understands that Janssen does not intend to update the strain composition of the vaccine to address emerging variants.

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revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

Because FDA understands that Janssen does not intend to offer the Janssen COVID-19 Vaccine in the United States under the EUA anymore and because Janssen requested that FDA revoke the EUA for the Janssen COVID-19 Vaccine, revocation of the EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the FD&C Act.

Regarding the disposition of expired Janssen COVID-19 Vaccine, healthcare providers and healthcare facilities can find information on disposal of expired lots on CDC's website. For example, refer to: COVID-19 Vaccination Provider Requirements and Support | CDC

In addition, Janssen submitted a proposal regarding submission of post authorization safety information, and submission of updated chemistry, manufacturing and control data currently required under the EUA conditions of authorization once the EUA 27205 has been revoked. FDA reviewed the proposal and requested changes, which Janssen agreed to implement.

III. Conclusion:

As noted above, FDA understands that Janssen does not intend to offer the Janssen COVID-19 Vaccine in the United States under the EUA anymore, and Janssen has requested that FDA withdraw the EUA for the Janssen COVID-19 Vaccine. In addition, Janssen's proposal for submission of certain information currently required under the EUA conditions of authorization has been deemed acceptable by FDA. Revocation of the EUA 27205 is appropriate to protect public health or safety under section 564(g)(2)(C) of the FD&C Act.

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