

June 1, 2023

Janssen Biotech, Inc. Attention: Ms. Ruta Walawalkar 920 Route 202 Raritan, NJ 08869

Re: Revocation of EUA 27205 - Janssen COVID-19 Vaccine

Dear Ms. Walawalkar:

This letter is in response to the request from Janssen Biotech, Inc. received on May 22, 2023, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the Janssen COVID-19 Vaccine issued on February 27, 2021, as subsequently amended. Janssen Biotech, Inc has informed the FDA that the last lots of the Janssen COVID-19 Vaccine purchased by the United States Government have expired, that there is no demand for new lots of the Janssen COVID-19 Vaccine in the United States, and that Janssen Biotech, Inc does not intend to update the strain composition of this vaccine to address emerging variants.

The authorization of a biological product for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because FDA understands that Janssen Biotech, Inc. no longer intends to offer the Janssen COVID-19 Vaccine in the United States under the EUA and because Janssen Biotech, Inc. has requested that FDA withdraw the EUA for the Janssen COVID-19 Vaccine, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 27205 for the Janssen COVID-19 Vaccine, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Janssen COVID-19 Vaccine is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the Federal Register, pursuant to section 564(h)(1) of the Act.

Sincerely,

Peter Marks, M.D, Ph.D. Director Center for Biologics Evaluation and Research