DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 29, 2021

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

Re: EUA 27205/56 - Requests for Amendments to Update the Authorized Health Care Provider Fact Sheet
Product Name: Janssen COVID-19 Vaccine
Dated: March 19, 2021
Received: March 19, 2021

Dear Ms. Walawalkar:

This letter is to notify you that your request is granted to modify the carton label to clarify that after first use, the Janssen Covid-19 vaccine may be held at 2°C to 8°C (36°F to 46°F) for up to 6 hours, or at room temperature (maximally 25°C/77°F) for up to 2 hours, as well as additional minor changes.

In addition, the EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been updated to clarify that: this vaccine is being made available for emergency use through the CDC COVID-19 Vaccination Program (the Vaccination Program); vaccinators may not charge vaccine recipients a fee, although they may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees; and how to report cases of suspected fraud. In addition, the EUA Fact Sheet for Recipients and Caregivers has been updated to clarify that those that receive a COVID-19 Vaccine cannot be charged, although providers may seek reimbursement from a program or plan that covers COVID-19 vaccine administration fees; and how to report cases of suspected fraud.

By submitting this amendment for review and concurrence by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the February 27, 2021, letter 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