

March 13, 2023

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

Dear Ms. Walawalkar:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).<sup>1</sup> On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.<sup>2</sup>

On February 27, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19 for individuals 18 years of age and older pursuant to Section 564 of the Act.

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<sup>1</sup> U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

FDA reissued the letter of authorization on June 10, 2021,<sup>3</sup> October 20, 2021,<sup>4</sup> November 19, 2021,<sup>5</sup> and May 5, 2022.<sup>6</sup>

On March 13, 2023, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the May 5, 2022 letter of authorization in its entirety to revise the conditions of authorization related to Vaccine Adverse Event Reporting System (VAERS) reporting requirements for vaccination providers and Janssen Biotech, Inc. to include myocarditis and pericarditis. Because some cases of myocarditis or pericarditis following vaccine administration may not meet the definition of serious adverse events, updating the VAERS reporting requirements helps to ensure that cases are reported by Janssen Biotech, Inc. and vaccination providers. FDA is also revising condition N to state that myocarditis and pericarditis are included in the pre-specified list of adverse events of special interest for post-authorization studies. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was updated to reflect the revision to the reporting requirements for vaccination providers, to include a new Warning for myocarditis and pericarditis (section 5.5), and to include facial paralysis (including Bell's palsy) in Section 6.2 as adverse reactions identified during post-authorization use. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Janssen COVID-19 Vaccine and to include weakness or paralysis of the muscles of the face in the section on risks of the Janssen COVID-19 Vaccine. FDA is also revising the scope of the booster dose authorization for

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<sup>3</sup> In the June 10, 2021 revision, FDA clarified the terms and conditions that relate to export of Janssen COVID-19 Vaccine from the United States.

<sup>4</sup> In the October 20, 2021 revision, FDA authorized for emergency use the administration of a single homologous booster dose of Janssen COVID-19 Vaccine at least 2 months after the primary vaccination to individuals 18 years of age or older, and authorized a single booster dose of the Janssen COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine. The eligible population(s) and dosing interval for the authorized heterologous booster dose were the same as those authorized for a booster dose of the vaccine used for primary vaccination.

<sup>5</sup> In the November 19, 2021 revision, FDA authorized the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals aged 18 years of age and older. The dosing interval for the authorized heterologous booster dose was the same as that authorized for a booster dose of the vaccine used for primary vaccination. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was updated to state that data support the effectiveness of a booster dose when administered at an interval of longer than 2 months after primary vaccination with the Janssen COVID-19 Vaccine.

<sup>6</sup> In the May 5, 2022 revision, FDA limited the authorized use of the vaccine to only include: 1) individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and 2) individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine. The vaccine is authorized for the prevention of COVID-19 for these individuals. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was updated to include: (i) the revised authorized use; (ii) at the beginning of the Fact Sheet, a warning statement summarizing information on the risk for thrombosis with thrombocytopenia syndrome (TTS), a potentially fatal adverse reaction that can be caused by the vaccine; (iii) updated reporting rate for TTS among females 30-49 years; and (iv) revisions to Patient Counseling Information. The Fact Sheet for Recipients and Caregivers was also updated to include the revised authorized use and the updated reporting rate for TTS among females 30-49 years.

the Janssen COVID-19 Vaccine so that it may be administered as a first booster dose at least 2 months after primary vaccination, regardless of which FDA-authorized or approved COVID-19 vaccine was received for primary vaccination. Specifically, for individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine, we are authorizing the Janssen COVID-19 Vaccine as a first booster dose administered at least 2 months after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. This accounts for the authorization of additional COVID-19 vaccines and changes made to the scope of authorization for other COVID-19 vaccines since the May 5, 2022 reissuance of this letter. The interval aligns with previously reviewed data on use of the Janssen COVID-19 Vaccine as a booster dose. The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were updated to reflect this revision.

For the February 27, 2021 authorization for individuals 18 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 3 trial which enrolled 43,783 participants randomized 1:1 to receive Janssen COVID-19 Vaccine or saline control. The trial enrolled participants 18 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization. FDA's review of the available safety data from 43,783 participants 18 years of age and older, who were followed for a median duration of eight weeks after receiving the vaccine or placebo, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the efficacy data from 39,321 participants 18 years of age and older who were SARS-CoV-2 seronegative or who had an unknown serostatus at baseline show that the vaccine was 66.9% effective (95% confidence interval (CI): 59.0, 73.4) and 66.1% effective (95% CI: 55.0, 74.8) in preventing moderate to severe/critical COVID-19 occurring at least 14 days and at least 28 days after vaccination, respectively. Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded it was reasonable to believe that the Janssen COVID-19 Vaccine may be effective. Additionally, FDA concluded, based on the totality of the scientific evidence available, that the known and potential benefits of the Janssen COVID-19 Vaccine outweigh its known and potential risks, for the prevention of COVID-19 in individuals 18 years of age and older. Finally, on February 26, 2021, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the October 20, 2021 authorization of a single booster dose of the Janssen COVID-19 Vaccine at least 2 months after administration of the primary vaccination, FDA reviewed, but did not independently verify, safety and effectiveness data from studies evaluating a booster dose of the Janssen COVID-19 Vaccine. Overall, in 5 clinical studies, approximately 9,000 participants have received 2 doses of the Janssen COVID-19 Vaccine, administered at least 2 months apart and approximately 2,700 participants had at least 2 months of safety follow-up after the booster dose. An overall assessment of Janssen's safety analyses from studies evaluating 2 doses of the Janssen COVID-19 Vaccine did not reveal new safety concerns following a booster dose, as compared with

adverse reactions reported following the single-dose primary vaccination. In a Phase 2 study, individuals 18 through 55 years of age and 65 years and older received a booster dose of the Janssen COVID-19 Vaccine approximately 2 months after the primary vaccination. Immunogenicity was assessed by measuring neutralizing antibodies to SARS-CoV-2 Victoria/1/2020 strain using a qualified wild-type virus neutralization assay. Available immunogenicity data from 39 individuals showed that the booster dose elicited geometric mean increases in neutralizing antibody titers of approximately 8-fold above pre-primary vaccination baseline and approximately 2-fold above pre-booster baseline. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trials, FDA concluded that a booster dose of the Janssen COVID-19 Vaccine may be effective, and that the known and potential benefits of a booster dose at least two months after the primary vaccination in individuals 18 years of age and older outweigh its known and potential risks. Finally, on October 15, 2021, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the October 20, 2021 authorization of a booster dose of the Janssen COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, FDA reviewed data from an ongoing Phase 1/2 clinical trial in participants 19-85 years of age. In this trial, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series (N=151), a Janssen COVID-19 Vaccine single dose (N=156), or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series (N=151) at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection were randomized 1:1:1 to receive a booster dose of one of three vaccines: Moderna COVID-19 Vaccine, Janssen COVID-19 Vaccine, or Pfizer-BioNTech COVID-19 Vaccine. Adverse events were assessed through 28 days after the booster dose. An overall review of adverse reactions reported following the Janssen COVID-19 Vaccine heterologous booster dose did not identify any new safety concerns, as compared with adverse reactions reported following a Janssen COVID-19 Vaccine primary vaccination or homologous booster dose. Neutralizing antibody titers, as measured by a pseudovirus neutralization assay using a lentivirus expressing the SARS-CoV-2 Spike protein with D614G mutation, were assessed on Day 1 prior to administration of the booster dose and on Day 15 after the booster dose. A booster response to the Janssen COVID-19 Vaccine was demonstrated regardless of primary vaccination. Based on the totality of the scientific evidence available, including data from the above-referenced clinical trial, FDA concluded that a heterologous booster dose of the Janssen COVID-19 Vaccine may be effective, and that the known and potential benefits of a heterologous booster dose of the Janssen COVID-19 Vaccine following completion of primary vaccination with another authorized or approved COVID-19 vaccine outweigh the known and potential risks of the vaccine.

For the November 19, 2021 authorization, Janssen's analysis of IgG binding antibody titers elicited by a booster dose administered 6 months after primary vaccination (submitted previously in support of the October 20, 2021, authorization) further supports effectiveness of a Janssen COVID-19 Vaccine homologous booster dose when

administered at an interval longer than 2 months after primary vaccination; thus, FDA has added a corresponding statement in the Fact Sheet for Healthcare Providers Administering Vaccine. Additionally, data previously reviewed to support the October 20, 2021 authorization of a heterologous booster dose, together with data and information to support the authorization of the EUA amendments to expand the eligible population for Pfizer-BioNTech and Moderna COVID-19 Vaccine homologous booster doses, support a revision to the Janssen COVID-19 Vaccine heterologous booster dose authorization to include all adults 18 years of age and older who completed primary vaccination with another authorized or approved COVID-19 vaccine. Based on the totality of the available scientific evidence, FDA concluded that a heterologous booster dose of the Janssen COVID-19 Vaccine may be effective, and that the known and potential benefits outweigh the known and potential risks for use of a heterologous booster dose of the Janssen COVID-19 Vaccine when administered to the eligible population, which now includes all individuals 18 years of age and older who have completed primary vaccination with this vaccine or with another authorized or approved COVID-19 vaccine, and where the dosing interval for the heterologous booster dose is the same as that authorized for a homologous booster dose of the vaccine used for primary vaccination.

For the May 5, 2022 revision limiting the authorized use to individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine, FDA conducted an updated analysis of TTS cases following administration of the Janssen COVID-19 Vaccine that were reported to the Vaccine Adverse Event Reporting System (VAERS) through March 18, 2022. Compared to a previous analysis conducted in December 2021, this analysis found additional cases of TTS, including another fatality, for a total of 60 confirmed cases and nine fatalities. The updated analysis found reporting rates of 3.23 cases of TTS and 0.48 TTS deaths per million administered doses of the Janssen COVID-19 Vaccine. Based on the Agency's updated analysis, the reporting rate of TTS and TTS deaths following administration of the Janssen COVID-19 Vaccine are not appreciably lower than those based on the prior Agency analysis. Based on this updated analysis, FDA has determined that the risk for TTS materially affects the risk/benefit assessment upon which the EUA was based, such that the known and potential benefits of the Janssen COVID-19 Vaccine when used to prevent COVID-19 outweigh the known and potential risks in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, or who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

## I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Janssen COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

- A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
- B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of the Janssen COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and
- C. There is no adequate, approved, and available alternative<sup>7</sup> to the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19.<sup>8</sup>

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Janssen Biotech, Inc. will supply the Janssen COVID-19 Vaccine, either directly or through authorized distributor(s)<sup>9</sup> to emergency response stakeholders<sup>10</sup> as directed by the U.S. government, including the Centers for Disease Control and

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<sup>7</sup> FDA continues to find that there is no adequate, approved, and available alternative to the Janssen COVID-19 Vaccine for the authorized population. Although Comirnaty (COVID-19 Vaccine, mRNA) and Spikevax (COVID-19 Vaccine, mRNA) are approved to prevent COVID-19 in individuals 12 years and 18 years of age and older, respectively, these may not be an adequate, approved, and available alternative for individuals for whom those vaccines are not accessible or clinically appropriate or who would not otherwise receive a COVID-19 vaccine.

<sup>8</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>9</sup> “Authorized Distributor(s)” are identified by Janssen Biotech, Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Janssen COVID-19 Vaccine.

<sup>10</sup> For purposes of this letter, “emergency response stakeholder” refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction’s COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among “emergency response stakeholders” and “vaccination providers” (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;

- The Janssen COVID-19 Vaccine may be administered by a vaccination provider<sup>11</sup> without an individual prescription for each vaccine recipient; and
- The Janssen COVID-19 Vaccine covered by this authorization will be administered by vaccination providers and used only to prevent COVID-19 in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine, and to provide:
  - a single dose primary vaccination; and
  - a first booster dose at least 2 months after completion of primary vaccination with any FDA authorized or approved COVID-19 vaccine.

## Product Description

The Janssen COVID-19 Vaccine is supplied as a suspension in multi-dose vials. The Janssen COVID-19 Vaccine does not contain a preservative.

Each 0.5 mL dose of the Janssen COVID-19 Vaccine is formulated to contain  $5 \times 10^{10}$  virus particles of the Ad26 vector encoding the S glycoprotein of SARS-CoV-2. Each dose of the Janssen COVID-19 Vaccine also includes the following inactive ingredients 2.19 mg sodium chloride, 0.14 mg citric acid monohydrate, 2.02 mg trisodium citrate dihydrate, 0.16 mg polysorbate-80, 25.5 mg 2-hydroxypropyl-B-cyclodextrin, 2.04 mg ethanol. Each dose may also contain residual amounts of host cell proteins ( $\leq 0.15$  mcg) and/or host cell DNA ( $\leq 3$  ng).

The manufacture of the authorized Janssen COVID-19 Vaccine is limited to those facilities identified and agreed upon in Janssen’s request for authorization.

The Janssen COVID-19 Vaccine vial label and carton labels are clearly marked for “Emergency Use Authorization.” The Janssen COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response

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<sup>11</sup> For purposes of this letter, “vaccination provider” refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder’s official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a “vaccination provider” is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, “healthcare provider” also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

The Janssen COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as “authorized labeling”):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)
- Fact Sheet for Recipients and Caregivers: Emergency Use Authorization (EUA) of the Janssen COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the Janssen COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the Janssen COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that the Janssen COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the Janssen COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), the Janssen COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

### III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

#### Janssen Biotech, Inc. and Authorized Distributor(s)

- A. Janssen Biotech, Inc. and authorized distributor(s) will ensure that the authorized Janssen COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.
- B. Janssen Biotech, Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.
- C. Janssen Biotech, Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving the authorized Janssen COVID-19 Vaccine. Janssen Biotech, Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.
- D. Janssen Biotech, Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.
- E. Janssen Biotech, Inc. may request changes to this authorization, including to the authorized Fact Sheets for the Janssen COVID-19 Vaccine. Any request for changes to this EUA must be submitted to the Office of Vaccines Research and Review (OVR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.<sup>12</sup>

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<sup>12</sup> The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. All changes to the authorization require review and concurrence from OVR. For

- F. Janssen Biotech, Inc. will report to VAERS:
- Serious adverse events (irrespective of attribution to vaccination);
  - Cases of myocarditis;
  - Cases of pericarditis;
  - Cases of Multisystem Inflammatory Syndrome in adults; and
  - Cases of COVID-19 that result in hospitalization or death, that are reported to Janssen Biotech, Inc.
- These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Janssen Biotech, Inc.
- G. Janssen Biotech, Inc. must submit to Investigational New Drug application (IND) number 22657 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Pharmacovigilance (OBPV)/CBER, beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
- A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
  - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
  - Newly identified safety concerns in the interval; and
  - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).
- H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.
- I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.
- J. Janssen Biotech, Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

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changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is also required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist.

- K. Janssen Biotech, Inc. will submit to the EUA file quarterly manufacturing reports that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report. The first report is due June 1, 2021.
- L. Janssen Biotech, Inc. and authorized distributor(s) will maintain records regarding release of Janssen COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).
- M. Janssen Biotech, Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.
- N. Janssen Biotech, Inc. will conduct post-authorization observational studies to evaluate the association between Janssen COVID-19 Vaccine and a pre-specified list of adverse events of special interest, including myocarditis and pericarditis, thrombosis with thrombocytopenia syndrome (TTS), Guillain-Barré syndrome, immune thrombocytopenia (ITP), along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Janssen COVID-19 Vaccine under this EUA in the general U.S. population (18 years of age and older), individuals who receive a booster dose, populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Janssen Biotech, Inc. will provide protocols and status update reports to the IND 22657 with agreed-upon study designs and milestone dates.

#### Emergency Response Stakeholders

- O. Emergency response stakeholders will identify vaccination sites to receive authorized Janssen COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.
- P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Fact Sheet for Recipients and Caregivers] is

made available to vaccination providers through appropriate means (e.g., e-mail, website).

- Q. Emergency response stakeholders receiving authorized Janssen COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

### Vaccination Providers

- R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

- S. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination.

- T. Vaccination providers administering the Janssen COVID-19 Vaccine must report the following information associated with the administration of the Janssen COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Cases of myocarditis
- Cases of pericarditis
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in adults
- Cases of COVID-19 that result in hospitalization or death

Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. The VAERS reports should include the words "Janssen COVID-19 Vaccine EUA" in the description section of the report. More information is available at [vaers.hhs.gov](https://vaers.hhs.gov) or by calling 1-800-822-7967. To the extent feasible, report to Janssen Biotech, Inc. by contacting 1-800-565-4008 or by providing a copy of the VAERS form to Janssen Biotech, Inc.; Fax: 215-293-9955, or by email [JNJvaccineAE@its.jnj.com](mailto:JNJvaccineAE@its.jnj.com).

- U. Vaccination providers will conduct any follow-up requested by the U.S. government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

- V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to

CDC.

- W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

- X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Janssen COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in Section 502(a) and (n) of the FD&C Act and FDA implementing regulations
- Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Condition Related to Export

- Z. If the product is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

#### IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

**Peter W.  
Marks -S**

 Digitally signed by Peter  
W. Marks -S  
Date: 2023.03.13 17:04:34  
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Peter Marks, M.D, Ph.D.  
Director  
Center for Biologics Evaluation and Research