

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 provider¹¹ 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 5×10^{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- β -cyclodextrin, 2.04 mg ethanol. Each dose may also contain residual amounts of host cell proteins (≤ 0.15 mcg) and/or host cell DNA (≤ 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

¹¹ 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.¹²

¹² 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.

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 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.

- 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,

--/S/--

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

REVOKED