Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21841 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2389]

Authorization of Emergency Use of a Biological Product in Response to an Outbreak of Monkeypox; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in response to an outbreak of monkeypox. FDA has issued one Authorization for a biological product as requested by the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the August 9, 2022, determination by the Secretary of the Department of Health and Human Services (HHS) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on August 9, 2022, that circumstances exist justifying the authorization of emergency use of vaccines pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of August 9, 2022.

ADDRESSES: Submit written requests for a single copy of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives (among other criteria).

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc).

FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) that an agent referred to in a declaration

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564 of the FD&C Act, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii) of the FD&C Act, that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(5) of the FD&C Act.

III. The Authorization

The Authorization follows the August 9, 2022, determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS declared, on August 9, 2022, that circumstances exist justifying the authorization of emergency use of vaccines pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's determination and declaration was provided in the **Federal Register** on August 15, 2022 (87 FR 50090). Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has issued the authorization for the emergency use of a biological product during the monkeypox outbreak. On August 9, 2022, FDA issued an EUA to NIAID for the biological product JYNNEOS, subject to the terms of the Authorization.

The initial Authorization, which is included below in its entirety after section IV of this document (not including the authorized versions of the fact sheets and other written materials), provides an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuance of the Authorization can be found on FDA's web page at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorization is available on the internet at: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

August 9, 2022

John Beigel, M.D.
Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases (NIAID)

Dear Dr. Beigel:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for FDA-unapproved emergency use of Jynneos, an FDA-approved vaccine, for the prevention of monkeypox disease in individuals determined to be at high risk of monkeypox infection. In response to this request and our review of available data, we are authorizing certain unapproved uses of Jynneos as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act) (21 U.S.C. 360bbb-3).

On August 9, 2022, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States (U.S.) citizens living abroad, and that involves monkeypox virus. On the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of vaccines for use against the monkeypox virus, pursuant to Section 564 of the Act, subject to terms of any authorization issued under that section.[1]

Jynneos is a live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus. Each 0.5 mL single dose is formulated to contain 0.5×10^8 to 3.95×10^8 infectious units of MVA-BN live virus. Jynneos is licensed for active immunization to prevent smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. It is FDA-approved as a two-dose series, with each 0.5 mL dose given subcutaneously (SC) 4 weeks apart.

For the authorization of intradermal administration of two doses (0.1 mL each) of Jynneos to individuals 18 years of age and older, FDA reviewed immunogenicity and safety data from a completed phase 2 trial in which 191 subjects received two intradermal (ID) doses of Jynneos (0.1 mL each), and 167 subjects received two SC doses of Jynneos (0.5 mL each). Study vaccinations were administered 4 weeks apart to all subjects. FDA's review of the available safety data did not identify specific safety concerns that would preclude issuance of an EUA. Following vaccination with Jynneos SC and ID immunogenicity was evaluated using 4 different

[1] U.S. Department of Health and Human Services, Determination of Public Health Emergency or Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b).

assays. Plaque reduction neutralizing antibody titers (PRNT) were obtained using assays performed at St. Louis University (SLU) and Bavarian-Nordic (BN) and enyzme linked immunosorbent assay (ELISA) values were obtained from assays conducted at SLU and BN. The development of the immune response to Jynneos over time following SC and ID administration was nearly identical, and the $\log_2$ transformed peak titers obtained following ID administration were non-inferior those obtained following SC administration. For the authorization of SC administration of two doses (0.5 mL each) of Jynneos to individuals younger than 18 years of age FDA has considered the available Jynneos safety and immunogenicity data in adults as well as the historical data with use of live vaccinia virus smallpox vaccine in pediatric populations. Based on these data, FDA concluded that it is reasonable to believe, based on the totality of scientific evidence available, that Jynneos may be effective and that the known and potential benefits of Jynneos outweigh the known and potential risks of the vaccine, for the prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk of monkeypox infection when two 0.5 mL doses are administered subcutaneously 4 weeks apart, and in individuals 18 years of age and older determined to be at high risk of monkeypox infection when two 0.1 mL doses are administered intradermally 4 weeks apart.

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 Jynneos for the prevention of monkeypox disease 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 Jynneos for the prevention of monkeypox disease 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:

1) The monkeypox virus can cause a serious or life-threatening disease or condition to humans infected by this virus;

2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the use of Jynneos under this authorization may be effective in preventing monkeypox disease, and that, when used under the conditions described in this authorization, the known and potential benefits of this use when used to prevent monkeypox disease outweigh its known and potential risks; and

3) There is no adequate, approved, and available alternative[2] for the unapproved uses of Jynneos to prevent monkeypox disease.[3]

---

[2] Although Jynneos is approved as a two-dose series (0.5 mL each) to prevent monkeypox disease in individuals 18 years of age and older determined to be at high risk of monkeypox infection, there is currently not sufficient quantities of this vaccine available for distribution to this population in its entirety using the approved route of administration. Additionally, Jynneos is not approved to provide vaccination in the pediatric population.

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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:

- Emergency uses of Jynneos covered by this authorization are supplied by the Administration for Strategic Preparedness & Response (ASPR) to emergency response stakeholders[4] consistent with the terms and conditions of this EUA;
- Use of Jynneos in accordance with this authorization will be administered by vaccination providers[5] and used only to prevent monkeypox disease in:
    1. individuals less than 18 years of age determined to be at high risk of monkeypox infection when two 0.5 mL doses are administered subcutaneously 4 weeks apart, and
    2. individuals 18 years of age and older determined to be at high risk of monkeypox infection when two 0.1 mL doses are administered intradermally 4 weeks apart.
- Jynneos may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

Product Description

Jynneos is supplied as a suspension and does not contain a preservative. Jynneos is approved for use in individuals 18 years of age and older. The FDA-approved dosing regimen is two doses (0.5 mL each) given subcutaneously 4 weeks apart. Under the license, Jynneos is supplied in a single dose vial.

Under this authorization, each vial contains a single dose (0.5 mL) for subcutaneous injection in individuals less than 18 years of age or up to 5 doses (0.1 mL each) for intradermal injection in individuals 18 years of age and older.

Jynneos 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"):

---

[4] 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 monkeypox vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers." In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[5] For purposes of this letter, "vaccination provider" refers to anyone who is licensed or otherwise authorized to administer or provide vaccination services (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) in accordance with the applicable emergency response stakeholder's official emergency response plan(s).

- Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization (EUA) of Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) for Prevention of Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection

- Fact Sheet for Recipients and Caregivers About Jynneos (Smallpox and Monkeypox Vaccine, Live, Non-Replicating) to Prevent Monkeypox Disease in Individuals Determined to be at High Risk for Monkeypox Infection

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 use of Jynneos under this authorization, when used to prevent monkeypox disease 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 use of Jynneos under this authorization may be effective in preventing monkeypox disease 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 use of Jynneos (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 authorized emergency use of Jynneos 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), use of Jynneos is authorized to prevent monkeypox disease as described in the Scope of Authorization (Section II) under this EUA, despite the fact that such use 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:

The Administration for Strategic Preparedness & Response (ASPR)

A. For distributions under this authorization, ASPR will distribute Jynneos under its direction to the extent such distributions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling.

B. ASPR will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. ASPR will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders and vaccination providers) involved in distributing or receiving Jynneos under this authorization. ASPR 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. ASPR 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. ASPR will maintain records regarding release of Jynneos for distribution (i.e., lot numbers, quantity, release date).

F. ASPR will make available to FDA upon request any records maintained in connection with this EUA.

National Institute of Allergy and Infectious Diseases (NIAID)

G. NIAID may request changes to this authorization, including to the authorized Fact Sheets for Jynneos. Any request for changes to this EUA must be submitted to the Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[6]

Bavarian Nordic A/S

H. Bavarian Nordic A/S will submit to the STN 125678 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 November

[6] 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 OVRR. For 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 (OCET)/Office of the Chief Scientist (OCS).

9, 2022. This EUA does not supersede requirements under the biologics license applicable to facilities, equipment, manufacturing, and lot release.

I. Bavarian Nordic A/S must submit reports to Vaccine Adverse Event Reporting System (VAERS) for the following:
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of cardiac events including myocarditis and pericarditis (regardless of seriousness or expectedness)
   - Cases of thromboembolic events and neurovascular events

   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 Bavarian Nordic A/S. All other adverse events must be submitted to VAERS as periodic (non-expedited) reports in compliance with 21 CFR 600.80.

J. Bavarian Nordic A/S must submit to STN 125678 periodic safety reports for Jynneos 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 must contain consolidated aggregate analysis for all postmarketing and post-authorization spontaneous adverse event reports, and 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).

Emergency Response Stakeholders

K. Emergency response stakeholders will identify vaccination sites to receive authorized Jynneos and ensure its distribution and administration, consistent with the terms of this letter.

L. 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 and Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

M. Emergency response stakeholders receiving Jynneos will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

N. Vaccination providers will administer the vaccine in accordance with the authorization.

O. Vaccination providers will provide the Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose.

P. Vaccination providers administering Jynneos must report the following information associated with the administration of Jynneos 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
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of cardiac events including myocarditis and pericarditis
   - Cases of thromboembolic events and neurovascular events

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Jynneos" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. Please also provide a copy of the VAERS form to Bavarian Nordic at 1-800-675-9596.

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

R. 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.

S. 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

T. All descriptive printed matter, advertising, and promotional material, relating to the use of Jynneos under this authorization 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.

Page 8 –Dr. Beigel, NIAID

U. All descriptive printed matter, advertising, and promotional material relating to the use of Jynneos under this authorization clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA for use in individuals less than 18 years of age, or as two 0.1 mL doses administered intradermally 4 weeks apart in individuals 18 years of age and older determined to be at high risk of monkeypox infection but has been authorized for emergency use by FDA, under an EUA to prevent monkeypox disease; 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.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of vaccines for use to prevent monkeypox disease 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 W. Marks, M.D., Ph.D.
Director
Center of Biologics Evaluation and Research
Food and Drug Administration

Enclosures

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21834 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2355]

Prescription Drug User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2023. These fees apply to the period from October 1, 2022, through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD, 301–796–7223; and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (G), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2023 is $1,151,522,958. The FY 2023 base revenue amount is adjusted for inflation, strategic hiring and retention, and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(F) of the FD&C Act) to provide for additional full-time equivalent (FTE) positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then