III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.*

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18517 Filed 8–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0895]

Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act, authorizes FDA to award priority review vouchers to sponsors of a material threat medical countermeasure application that meets certain criteria upon approval of such application. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the application for MOUNJARO (tirzepatide) injection, approved May 13, 2022, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8515 (this is not a toll-free number), email: *EUA.OCET@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by section 3086 of the 21st Century Cures Act (Pub. L. 114–255), FDA will report the issuance of material threat medical countermeasure priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for MOUNJARO (tirzepatide) injection, approved May 13, 2022, meets the redemption criteria.

For further information about the Material Threat Medical Countermeasure Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions.* For further information about MOUNJARO (tirzepatide) injection, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: August 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18523 Filed 8–26–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0335]

Authorization of Emergency Use of a Biological Product During the COVID–19 Pandemic; 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) for use during the COVID–19 pandemic. FDA has issued one Authorization for a biological product as requested by Novavax, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized product. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, 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 July 13, 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,