4164-01-P

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.

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