



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-0015]

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat medical countermeasure (MCM) priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a voucher. FDA has determined that QULIPTA (atogepant) tablets, approved September 28, 2021, meets the redemption criteria.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1394, email: [Cathryn.Lee@fda.hhs.gov](mailto:Cathryn.Lee@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for QULIPTA (atogepant) tablets, approved September 28, 2021, meets the redemption criteria.

For further information about the material threat MCM 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#prv>. For further information about QULIPTA (atogepant) tablets go to the “Drugs@FDA” website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: January 17, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024-01108 Filed: 1/19/2024 8:45 am; Publication Date: 1/22/2024]