



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1262]

Notice of Approval of Product under Voucher: Material Threat Medical Countermeasure Priority Review Voucher; EYLEA HD (aflibercept)

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) authorizes FDA to award priority review vouchers to sponsors of approved material threat medical countermeasure (MCM) product applications that meet certain criteria. 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 EYLEA HD (aflibercept), approved August 18, 2023, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Andrea Gormley, Counter-Terrorism and Emergency Coordination Staff, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., 2nd Floor, Silver Spring, MD 20993-0002, 301-796-2210 (this is not a toll free number).

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 EYLEA HD (aflibercept) 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 EYLEA HD (aflibercept), go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: April 16, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-06969 Filed: 4/22/2025 8:45 am; Publication Date: 4/23/2025]