4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-0647]

Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product; EBANGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. 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 award of the priority review voucher. FDA has determined that EBANGA (ansuvimab-zykl) for injection, approved on December 21, 2020, manufactured by Ridgeback Biotherapeutics, LP, meets the criteria for a material threat MCM 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: FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined EBANGA (ansuvimab-zykl), manufactured by Ridgeback Biotherapeutics, LP, meets the criteria for a

material threat MCM priority review voucher. EBANGA was approved on December 21, 2020, for the treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Zaire ebolavirus* infection.

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 EBANGA (ansuvimab-zykl) for injection, 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.

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