



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-3500]

Notice of Approval of Product Under Priority Review Voucher; Material Threat Medical Countermeasure Priority Review Voucher; MRESVIA (Respiratory Syncytial Virus Vaccine)

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 priority review voucher. FDA has determined that MRESVIA (Respiratory Syncytial Virus Vaccine), approved May 31, 2024, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, industry.biologics@fda.hhs.gov, 240-402-7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a material threat MCM priority review voucher. 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 MRESVIA (Respiratory Syncytial Virus Vaccine), 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 MRESVIA (Respiratory Syncytial Virus Vaccine), go to the Center for Biologics Evaluation and Research Approved Products website at <https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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