4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-3446]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of rare pediatric disease priority review vouchers as well as the approval of products redeeming vouchers. FDA has determined that AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted), BLA supplement approved June 7, 2024, meets the criteria for redeeming a priority review voucher.

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 rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to

https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm. For further information about AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted), 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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