

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; FAYUVI (rebisufligene etisparvovec-hopf)

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The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. 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 award of the priority review voucher. FDA has determined that FAYUVI (rebisufligene etisparvovec-hopf), approved on September 17, 2026, manufactured by Ultragenyx Pharmaceutical Inc., meets the criteria for a priority review voucher.

Agency: Health and Human Services Department, Food and Drug Administration.

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