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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA- 2026-N-4573]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; AVLAYAH (tividenofusp alfa-eknm)

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 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 AVLAYAH (tividenofusp alfa-eknm), approved March 24, 2026, manufactured by Denali Therapeutics Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Room 5324, Silver Spring, MD 20993-0002, 301-796-2771, Quyen.Tran1@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined AVLAYAH (tividenofusp alfa-eknm), manufactured by Denali Therapeutics Inc., meets the criteria for a priority review voucher. AVLAYAH (tividenofusp alfa-eknm) injection is indicated for the treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when

initiated in presymptomatic or symptomatic pediatric patients weighing at least 5 kg prior to advanced neurologic impairment.

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 AVLAYAH (tividenofusp alfa-eknm), go to the "Drugs@FDA" website at https://www.accessdata.fda.gov/scripts/cder/daf/.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
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