4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-4682]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a 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 priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph), approved September 19, 2025, meets the criteria for redeeming 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 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 KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph) 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 KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph), go to the "Drugs@FDA" website at https://www.accessdata.fda.gov/scripts/cder/daf/.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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