Withdrawal of approval of PEPAXTO (NDA 214383) was effective February 23, 2024; the withdrawal includes all amendments and supplements to the application. As discussed in the decision of the Commissioner's designee, FDA has withdrawn approval of the PEPAXTO NDA for reasons of safety or effectiveness.

Section 505(j)(7) of the FD&C Act (21 U.S.C. 355(j)(7)) requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book,'' available at *https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.* Pursuant to section 505(j)(7)(C) of the FD&C Act, drugs are removed from the list if FDA determines that the listed drug has been withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency has removed the application for PEPAXTO from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that reference PEPAXTO.

II. Electronic Access

Persons with access to the internet may obtain the final decision at *https://downloads.regulations.gov/FDA-2023-N-3167-0049/attachment_1.pdf.* The final decision and other documents pertaining to the withdrawal of the NDA for PEPAXTO (NDA 214383) are available at *https://www.regulations.gov* under the docket number found in brackets in the heading of this document.

Dated: April 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08274 Filed 4–17–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1636]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; LENMELDY (Atidarsagene Autotemcel)

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 LENMELDY (atidarsagene autotemcel), approved on March 18, 2024, manufactured by Orchard Therapeutics (Europe) Ltd., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

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 that LENMELDY (atidarsagene autotemcel), manufactured by Orchard Therapeutics (Europe) Ltd., meets the criteria for a priority review voucher.

LENMELDY (atidarsagene autotemcel) is indicated for treatment of children with pre-symptomatic late infantile, pre-symptomatic early juvenile, or early symptomatic early juvenile metachromatic leukodystrophy.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about LENMELDY (atidarsagene autotemcel), go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: April 15, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–08276 Filed 4–17–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4804]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expedited Programs for Serious Conditions—Drugs and Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 20, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0765. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expedited Programs for Serious Conditions—Drugs and Biologics

OMB Control Number 0910–0765—Extension

This information collection supports regulations governing FDA expedited programs for serious conditions. These provisions are set forth in 21 CFR part 312, subpart E and are intended to speed the availability of new therapies to patients with serious conditions, especially when there are no satisfactory