contact Candace Carter at 410–786–8446.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–08223 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–3167]

Final Decision on Withdrawal of PEPAXTO (melphalan flufenamide) Following Appeal of the Proposal To Withdraw Approval; Availability of Final Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the final decision withdrawing approval of PEPAXTO (melphalan flufenamide), for injection, equivalent to 20 milligrams (mg) base/vial, once every 28 days, under the new drug application (NDA) 214383, held by Oncopeptides AB (Oncopeptides). The Commissioner of Food and Drugs' (the Commissioner's) designee issued the decision, and a summary of responses to public comments. The Commissioner's designee issued this decision following the Center for Drug Evaluation and Research's (CDER) proposal to withdraw approval of PEPAXTO, Oncopeptides' appeal of the proposed withdrawal, a meeting between the designee and Oncopeptides, a public comment period on the proposed withdrawal, and an advisory committee that CDER convened and consulted on issues related to the proposed withdrawal.

DATES: Approval of PEPAXTO is withdrawn as of February 23, 2024.

FOR FURTHER INFORMATION CONTACT: Anuj Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6224, Silver Spring, MD 20993–0002, 301–796–3600, *Anuj.Shah@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On February 26, 2021, FDA approved NDA 214383 for PEPAXTO (melphalan flufenamide) for injection, for use in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody (triple class refractory). FDA approved PEPAXTO under the accelerated approval pathway, pursuant to section 506(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)) and 21 CFR 314.510, based on evidence of the drug's effect on an intermediate clinical endpoint that was considered reasonably likely to predict the drug's clinical benefit.

As a condition of PEPAXTO's approval, the sponsor was required to complete a postapproval confirmatory trial to verify and describe the clinical benefit of PEPAXTO. The postapproval confirmatory trial, Trial OP–103, failed to meet the primary endpoint of progression-free survival superiority compared to the control arm and demonstrated a lower median overall survival compared to the control arm.

On September 22, 2022, an Oncologic Drugs Advisory Committee (ODAC) meeting was held to discuss the results of Trial OP–103. The committee discussed issues that were ultimately related to the withdrawal, including the progression-free survival results, overall survival results, dosing concerns, subpopulation considerations, and the benefit-risk profile of PEPAXTO for the patient population for which the drug was indicated. The ODAC voted 14 to 2 that the benefit-risk profile of PEPAXTO was not favorable for the patient population for which the drug was indicated.

On July 7, 2023, pursuant to the expedited withdrawal procedures under section 506(c)(3)(B) of the FD&C Act, CDER provided due notice to Oncopeptides of the proposal to withdraw approval of PEPAXTO on two independent grounds: (1) the postapproval confirmatory trial failed to verify clinical benefit and (2) the evidence demonstrates that the drug is not shown to be safe or effective under its conditions of use. CDER's notice provided Oncopeptides with an explanation for the proposed withdrawal, and advised Oncopeptides that it had the opportunity for a written appeal to and a meeting with the Commissioner, or the Commissioner's designee, regarding CDER's proposal.

On July 26, 2023, Oncopeptides submitted a letter indicating an intent to appeal the proposal to withdraw approval and requesting a meeting with the FDA Commissioner or the Commissioner's designee with respect to the proposed withdrawal of approval.

On August 4, 2023, Oncopeptides submitted its written appeal of CDER's proposal to withdraw approval of PEPAXTO. On August 9, 2023, Dr. Peter Marks, Director, Center for Biologics Evaluation and Research, notified the parties that the Commissioner had designated him to serve as the Commissioner's designee under section 506(c)(3)(B) of the FD&C Act. CDER submitted a response to Oncopeptides' written appeal on September 8, 2023, and Oncopeptides replied to CDER's response on September 19, 2023. On September 29, 2023, CDER submitted a response to Oncopeptides' September 19, 2023, correspondence. On October 2, 2023, Oncopeptides and CDER met with the Commissioner's designee, and both Oncopeptides and CDER submitted additional information requested by the designee after the meeting.

Consistent with the expedited withdrawal procedures under section 506(c)(3)(B) of the FD&C Act, CDER issued on August 25, 2023, a Notice of Opportunity for Public Comment on its proposal to withdraw PEPAXTO; the comment period remained open until September 25, 2023. The September 22, 2022, ODAC meeting had previously discussed and provided recommendations on issues with respect to the withdrawal of PEPAXTO.

On February 23, 2024, after reviewing the record and considering the arguments on appeal, the Commissioner's designee issued a final decision finding the grounds for withdrawal were met and that withdrawal was appropriate, withdrawing approval of PEPAXTO.

FDA has thus withdrawn approval of the following NDA:

Application No.	Drug	Holder/Sponsor
NDA 214383	Pepaxto (melphalan flufenamide) for Injection	Oncopeptides AB.

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