burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 24, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10143 State Data for the Medicare Modernization Act (MMA)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Data for the Medicare Modernization Act (MMA); *Use:* The monthly data file is provided to CMS by states on dual eligible beneficiaries. The phase-down process requires a monthly count of all full benefit dual eligible beneficiaries with an active Part D plan enrollment in the month. CMS will make this selection of records using dual eligibility status codes contained in the person-month record to identify all full-benefit dual eligible beneficiaries. *Form Number:* CMS–10143 (OMB Control Number: 0938–0958); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 4,896. (For policy questions regarding this collection contact Linda King at 410–786–1312.)

Dated: August 22, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–18387 Filed 8–24–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10305]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice, correction.

SUMMARY: On August 11, 2023, CMS published a notice in the **Federal Register** that sought comment on a collection of information concerning CMS–10305 (OMB control number 0938–1115) entitled ''Medicare Part C and Part D Data Validation.'' The point of contact for policy questions is incorrect. This document corrects the error.

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the August 11, 2023, issue of the **Federal Register** (88 FR 54613), we published a Paperwork Reduction Act notice requesting a 30-day public comment period for the information collection request identified under CMS–10305, OMB control number 0938–1115, and titled ''Medicare Part C and Part D Data Validation.''

II. Explanation of Error

In the August 11, 2023, notice, the point of contact for policy questions is incorrect. The incorrect language is on located at the top of the right column on page 54614, beginning on line 6 with ''Chanelle Jones'' and ending at the end of line 6. All of the other information contained in the August 11, 2023, notice is correct and remains unchanged. The related public comment period remains in effect and ends September 11, 2023.

III. Correction of Error

In FR Doc. 2023–16804 of August 11, 2023, (88 FR 54613), page 54614, the language at the top of the right column beginning on line 6 with ''Chanelle Jones'' and ending at the end of line 6, is corrected to read as follows:

Abigale Sanft at 410–786–6068.

Dated: August 21, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–18279 Filed 8–24–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3167]

Notice of Opportunity for Public Comment on Proposal To Withdraw Approval of New Drug Application for PEPAXTO, Equivalent to 20 Milligrams Base per Vial

AGENCY: Center for Drug Evaluation and Research, Food and Drug Administration, HHS.

ACTION: Notice of opportunity for public comment.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA, the Agency) is proposing to withdraw approval of PEPAXTO (melphalan flufenamide) for injection, equivalent to (EQ) 20 milligrams (mg) BASE/VIAL, once every 28 days, new drug application (NDA) 214383, held by Oncopeptides AB (Oncopeptides). This notice is intended to provide an opportunity for public comment on CDER's proposed withdrawal of PEPAXTO, in accordance with the expedited withdrawal of approval procedures described in the Federal Food, Drug and Cosmetic Act (FD&C Act).

DATES: Either electronic or written comments on this proposal to withdraw PEPAXTO must be submitted by September 25, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 25, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–3167 for ''Notice of Opportunity for Public Comment on Proposal To Withdraw Approval of New Drug Application for PEPAXTO, Equivalent to 20 Milligrams Base per Vial.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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, 301–796–2246.

SUPPLEMENTARY INFORMATION:

I. Background

FDA approved NDA 214383 for PEPAXTO on February 26, 2021, under the accelerated approval pathway (section 506(c) of the FD&C Act (21 U.S.C. 356(c)) and 21 CFR part 314, subpart H) 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 drug, and one CD38-directed monoclonal antibody (triple class refractory).[1]

NDA 214383 relied on evidence from Trial OP–106 (ClinicalTrials.gov NCT number, NCT02963493), also known as HORIZON, a single-arm, open-label, phase 2 multicenter clinical trial that enrolled patients with relapsed or refractory multiple myeloma and who received at least two lines of prior therapy including an immunomodulatory drug and a proteasome inhibitor. The primary endpoint was overall response rate (ORR),[2] as assessed by the investigator.

At the time of approval under the accelerated approval pathway, the applicant was required to conduct an appropriate post-approval study to verify and describe the clinical benefit of PEPAXTO.[3] CDER has determined

[1] Most patients in the United States with relapsed disease will have been exposed to lenalidomide (an immunomodulatory agent), a proteasome inhibitor, corticosteroids, and an anti-CD38 monoclonal antibody after one or two lines of treatment, and retreatment with previously used agents or agents in the same class of drug can be effective.

[2] ORR was defined as the proportion of patients with a best confirmed response of stringent complete response, complete response, very good partial response, or partial response according to the International Myeloma Working Group Uniform Response Criteria.

[3] Section 506(c)(2)(A)(i) of the FD&C Act (as renumbered by the Consolidated Appropriations

Continued

withdrawal of approval is warranted because the required post-approval confirmatory trial failed to verify clinical benefit and because available evidence demonstrates PEPAXTO is not shown to be safe or effective under its conditions of use. The Oncologic Drugs Advisory Committee (ODAC) convened on September 22, 2022, to discuss issues related to this proposed withdrawal. The ODAC voted 14 to 2 that the benefit-risk profile of melphalan flufenamide was not favorable for the currently indicated patient population. For additional background, please refer to CDER's letter to Oncopeptides Re: Section 506(c)(3)(B) Notice of Proposed Withdrawal of Approval; PEPAXTO (melphalan flufenamide) for injection; NDA 214383 (''Notice to Oncopeptides of Proposed Withdrawal of PEPAXTO'') and CDER's Proposed Withdrawal of PEPAXTO Decisional Memorandum, available at Docket No. FDA–2023–N–3167, *https://www.regulations.gov*.

II. Legal Standard for Withdrawal of Approval

Section 506(c) of the FD&C Act, as amended most recently by the Consolidated Appropriations Act of 2023 (Pub. L. 117–328), describes the accelerated approval of new drug applications and the procedures and authority governing expedited withdrawal of approval. FDA has the legal authority to use the expedited procedures to withdraw approval of a product that has received accelerated approval if, among other reasons, ''a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit'' (section 506(c)(3)(A)(ii) of the FD&C Act) or ''other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use.'' (section 506(c)(3)(A)(iii) of the FD&C Act.)

III. Explanation for the Proposed Withdrawal

CDER proposes to withdraw approval of PEPAXTO because the required confirmatory study, Trial OP–103, also known as OCEAN, failed to verify clinical benefit and because available evidence demonstrates PEPAXTO is not shown to be safe or effective under its conditions of use. More specifically, the results failed to show that PEPAXTO had a significant effect on the primary endpoint of progression-free survival. Furthermore, the observed median overall survival was 5.3 months shorter in the PEPAXTO arm compared to the control arm. After considering all the available data and the discussion at the ODAC held in September 2022, CDER recommends withdrawing the accelerated approval for PEPAXTO. Please refer to CDER's ''Notice to Oncopeptides of Proposed Withdrawal of PEPAXTO'' and ''Proposed Withdrawal of PEPAXTO Decisional Memorandum'' for additional explanation.

IV. Opportunity for Public Comment on CDER's Proposal To Withdraw Approval of PEPAXTO

In accordance with the expedited withdrawal of approval procedures described in section 506(c)(3)(B)(ii) and (iii) of the FD&C Act, CDER is providing an opportunity for public comment on its proposal to withdraw approval of NDA 214383 (PEPAXTO) through the issuance of a **Federal Register** Notice. FDA will consider any such public comments it receives in making its decision on CDER's proposal to withdraw approval of NDA 214383 (PEPAXTO) and make available on its website and in the public docket a summary of such comments and FDA's response to them.

Dated: August 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18320 Filed 8–24–23; 8:45 am]

BILLING CODE 4164–01–P

Act of 2023 (Pub. L. 117–328); see also 21 CFR 314.510.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Standardized Work Plan Form for Use With Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 24, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Standardized Work Plan (SWP) Form for Use with Applications to the Bureau of Health Workforce (BHW) Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Extension.

Abstract: BHW requires applicants for training and research grants and cooperative agreements to submit work plans via the SWP form. Information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement. Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. After awards are made, recipients complete a Quarterly Progress Update (QPU) to provide information to BHW on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: Information collected by the SWP form and QPUs standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve each of the objectives proposed during the entire period of performance. The current standardized format and data submission by applicants increases efficiency in reviewing, awarding, and monitoring each project.

The QPU is completed via HRSA's Electronic Handbook system and