Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, *mcabeza@fdic.gov,* MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

1. *Title:* Industrial Banks and Industrial Loan Companies.

OMB Number: 3064–0213.

Forms: None.

Affected Public: Prospective parent companies of industrial banks and industrial loan companies.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN (OMB NO. 3064–0213)

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
1. Initial Listing of Subsidiaries, 12 CFR 354.4(a)(1) (Mandatory).	Reporting (On Occasion).	2	1	04:00	8
2. Annual Update of Subsidiaries List, 12 CFR 354.4(a)(1) (Mandatory).	Reporting (Annual)	2	1	04:00	8
3. Annual Report of Covered Company and Subsidiaries and Other Reports as the FDIC may require, 12 CFR 354.4(a)(3) (Mandatory).	Reporting (Annual)	2	1	10:00	20
4. Recordkeeping requirements in written agreement, 12 CFR 354.4(a)(4) (Mandatory).	Recordkeeping (Annual)	2	1	10:00	20
5. Contingency Plan, 12 CFR 354.4(b) (Mandatory).	Reporting (Annual)	1	1	345:00	345
Total Annual Burden (Hours)	.....	.....	.....	.....	401

General Description of Collection: Part 354 of the FDIC regulations (part 354) establishes filing requirements for industrial banks or industrial loan companies (ILCs) and companies that are not subject to Federal consolidated supervision by the Federal Reserve Board but control an industrial bank or an ILC (covered company). Specifically, part 354 requires any covered company and industrial bank or ILC subsidiary of a covered company to enter into one or more written agreements with the FDIC. However, the requirements under part 354 do not apply to any industrial bank subsidiaries of covered companies that were subsidiaries of covered companies prior to the effective date of part 354—April 1, 2021. The requirements under part 354 give rise to this information collection.

The total estimated annual burden for this information collection is 401 hours, which is a decrease of 56 hours from the 2021 information collection submission (457 hours). This decrease is a result of a reduction in the estimated annual number of respondents.

Request for Comment: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on April 12, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024–08255 Filed 4–17–24; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10891 and CMS–R–285]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our 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 June 17, 2024.

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–10891 Medicaid Program; Medicare Savings Program Application and Eligibility Determinations

CMS–R–285 Medicare Request for Retirement Benefit Information

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicaid Program; Medicare Savings Program Application and Eligibility Determinations; *Use:* The provisions in this collection of information request are necessary for helping to enroll individuals into the Medicare Savings Programs (MSPs) as directed by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) and for implementing the September 21, 2023 (88 FR 65230) final rule entitled, ''Streamlining Medicaid: Medicare Savings Program Eligibility Determination and Enrollment'' (hereinafter ''MSP final rule'') (CMS–2421–F; RIN 0938–AU00).

CMS did not previously estimate several costs for implementing the provisions of MIPPA related to MSPs as well as costs related to MSPs that were longstanding costs inherent to the Medicaid program that predated MIPPA. To address that oversight, we estimate such burden in this collection of information request. We also estimate burden and savings associated with the provisions in the MSP final rule. Such burden was set out in the Regulatory Impact Analysis section of the final rule.

The MSPs are essential to the health and well-being of those enrolled, promoting access to care and helping free up individuals' limited income for food, housing, and other life necessities. Through the MSPs, Medicaid pays Medicare Part B premiums each month for over 10 million individuals and Part A premiums for over 700,000 individuals. State Medicaid agencies receive applications and adjudicate eligibility for MSP coverage.

MIPPA created new requirements for states to leverage the Medicare Part D Low-Income Subsidy (LIS) program to help enroll likely-eligible individuals in MSPs, and the MSP final rule expanded those requirements. States use information collected by the Social Security Administration on the LIS application (transmitted to states with the consent of an individual completing an application) to determine eligibility for the MSPs. Under the MSP final rule, the state Medicaid agency accepts and verifies the information provided on the LIS application (to the extent allowable under the MSP final rule); communicates with the applicant or the authorized representative about any additional information needed to make an MSP determination; makes the MSP eligibility determination; enrolls the individual in an MSP, if eligible; and informs the individual about the rights and responsibilities for applying for full Medicaid eligibility. Applicants include anyone who chooses to apply for LIS and provides consent for their application to be considered for MSPs.

In addition to building on MIPPA and strengthening the LIS pathway for enrolling in MSPs, the MSP final rule streamlined MSP eligibility and enrollment processes, reduced administrative burden on states and applicants, and increased enrollment and retention of eligible individuals.

Form Number: CMS–10891 (OMB control number: 0938–TBD); *Frequency:* Occasionally; *Affected Public:* State, Local and Tribal Governments and Individuals or households; *Number of Respondents:* 3,460,750; *Total Annual Responses:* 3,460,750; *Total Annual Hours:* 3,255,668. (For policy questions regarding this collection contact: Melissa Heitt at 410–786–2484.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Request for Retirement Benefit Information; *Use:* Medicare Premium Part A is a voluntary program that is financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government. Form CMS–R–285, ''Medicare Request for Retirement Benefit Information,'' is used to obtain information regarding whether a beneficiary currently purchasing Medicare Premium Part A coverage is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan is subsidizing the individual's Part A premium.

Form CMS–R–285 provides the necessary information regarding the prior state or local government employment to process the individual's request for premium Part A reduction based on their employment by a state or local government. The form is completed by the state or local government employer on behalf of the individual seeking the Medicare premium reduction. The SSA, CMS' agent for processing Medicare enrollments and premium amount determinations, will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. The form is owned by CMS but not completed by CMS staff. *Form Number:* CMS–R–285 (OMB control number: 0938–0769); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this collection

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]

BILLING CODE 4120–01–P

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.