Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–02683 Filed 2–8–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10291, CMS–10529, CMS–10722, and CMS–R–148]

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 April 9, 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–10291 State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Website and Hotline

CMS–10529 Quarterly Medicaid and CHIP Budget and Expenditure Reporting for the Medical Assistance Program, Administration and CHIP

CMS–10722 Annual State Report on CMS Value Based Purchasing Arrangements (VBP) Supplemental Rebate Agreements

CMS–R–148 Limitations on Provider Related Donations and Health Care Related Taxes, Medicaid and Supporting Regulations in 42 CFR 433.68 through 433.74

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: Extension without change of a currently approved collection; *Title of Information Collection:* State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Website and Hotline; *Use:* On the Insure Kids Now (IKN) website, the Secretary is required to post a current and accurate list of dentists and providers that provide dental services to children enrolled in the State plan (or waiver) under Medicaid or the State child health plan (or waiver) under CHIP. States collect the information pertaining to their Medicaid and CHIP dental benefits. *Form Number:* CMS–10291 (OMB control number: 0938–1065); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; Total Annual Responses: 255; *Total Annual Hours:* 11,781. (For policy questions regarding this collection contact Andrew Snyder at 410–786–1274.)

2. Type of Information Collection Request: Extension without change of a currently approved collection; *Title of Information Collection:* Quarterly Medicaid and CHIP Budget and Expenditure Reporting for the Medical Assistance Program, Administration and CHIP; *Use:* The Medicaid and CHIP Financial System is a financial reporting system that produces budget estimate statements for Forms CMS–37 and CMS–21B. The Medicaid and CHIP Budget and Expenditure System is a financial reporting system that produces expenditure statements for Forms CMS–64 and CMS–21. All forms are to be filed on a quarterly basis and need to be certified by the States. *Form Number:* CMS–10529 (OMB control number: 0938–1265); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 672; *Total Annual Hours:* 18,144. (For policy questions regarding this collection contact Robert Lane at 410–786–2015.)

3. Type of Information Collection Request: Revision of a currently approved collection; *Title of Information Collection:* Annual State Report on CMS Value Based Purchasing Arrangements (VBP) Supplemental Rebate Agreements; *Use:* The reported data is being collected to safeguard against unnecessary utilization of such care and services and to assure that State payments to providers of Medicaid

services are consistent with efficiency, economy, and quality of care. CMS will collect this data to ensure that VBP programs adopted by States continue to meet these standards. *Form Number:* CMS–10722 (OMB control number: 0938–1385); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 306. (For policy questions regarding this collection contact Abraham Weinschneider at 410–786–5688.)

4. Type of Information Collection Request: Extension without change of a currently approved collection; *Title of Information Collection:* Limitations on Provider Related Donations and Health Care Related Taxes, Medicaid and Supporting Regulations in 42 CFR 433.68 through 433.74; *Use:* States may elect to submit a waiver to CMS for the broad based and/or uniformity requirements for any health care related tax program which does not conform to the broad based and uniformity requirements. It is also the responsibility of each State to demonstrate that their tax program(s) do not violate the hold harmless provision. For a waiver to be approved and a determination that the hold harmless provision is not violated, States must submit written documentation which satisfies the regulatory requirements. Without this information, the amount of FFP (Federal financial participation) payable to a State cannot be correctly determined. *Form Number:* CMS–R–148 (OMB control number: 0938–0618); *Frequency:* Quarterly and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 40; *Total Annual Hours:* 3,200. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

William N. Parham, III

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

[FR Doc. 2024–02662 Filed 2–8–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–4279]

Determination That QMIIZ (Meloxicam) Orally Disintegrating Tablets, 7.5 Milligrams and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 milligrams (mg) and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3507, *Nicole.Mueller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, are the subject of NDA 211210, held by TerSera Therapeutics LLC (TerSera), and initially approved on October 19, 2018. QMIIZ is a non-steroidal anti-inflammatory indicated for osteoarthritis in adults, rheumatoid arthritis in adults, and pauciarticular or polyarticular course juvenile rheumatoid arthritis in pediatric patients who weigh greater than or equal to 60 kilograms.

In a letter dated March 24, 2021, TeraSera notified FDA that QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Pharmobedient Consulting submitted a citizen petition dated September 27, 2023 (Docket No. FDA–2023–P–4279), under 21 CFR 10.30, requesting that the Agency determine whether QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was