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Determination That QMIIZ (Meloxicam) Orally Disintegrating Tablets, 7.5 Milligrams and 15 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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or Agency) has determined that QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 milligrams (mg) and 15 mg, were not withdrawn from sale for reasons of safety or effectiveness.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

not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to QMIIZ (meloxicam) Orally Disintegrating Tablets, 7.5 mg and 15 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–02710 Filed 2–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0014]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. This meeting will be held to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2024 to 2025 influenza season. The meeting will be open to the public.

DATES: The meeting will be held virtually on March 5, 2024, from 9 a.m. to 3:30 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtube.com/live/Wf0aE32DPKc.*

Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2024–N–0014. The docket will close on March 4, 2024. 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 March 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before February 26, 2024, will be provided to the committee. Comments received on or after February 26, 2024, and by March 4, 2024, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

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–2024–N–0014 for ''Vaccines and Related Biological Products Advisory Committee (VRBPAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.