technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 806 [42 U.S.C. 2991d–1](a)(1) and Sec. 811 [42 U.S.C. 2992].

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–26230 Filed 11–12–24; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5057]

Public Workshop on Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public workshop titled ''Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward.'' The purpose of the public workshop is to provide interested parties with an update on FDA's current activities related to real-world evidence (RWE) and to share accomplishments, ongoing challenges, and future opportunities. The public workshop will discuss potential next steps to promote the continued evolution and consistent application of real-world data (RWD) in drug development. This public workshop will be convened and supported by a cooperative agreement between FDA and the Duke University, Duke-Margolis Institute for Health Policy.

DATES: The public workshop will be held on December 12, 2024, from 12:30 p.m. to 5 p.m., Eastern Time. Either electronic or written comments on this public workshop must be submitted by January 13, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in-person at the Bethesda North Marriott & Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852 and virtually using the Zoom platform.

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 January 13, 2025. 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–2024–N–5057 for ''Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward.'' 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: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov* or *CDER-RWE@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The volume and complexity of RWD available to support drug development have increased substantially over the past several decades. This increase, combined with enhanced computing power and emerging technologies, is transforming how drugs are developed.

FDA published a ''Framework for FDA's Real-World Evidence Program'' (Framework) (*https://www.fda.gov/media/120060/download?attachment*) for drugs and biological products in 2018. This Framework describes a multifaceted FDA program to evaluate the potential use of RWE in regulatory decision-making to help support the approval of a new indication for a drug already approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c)) or to help support or satisfy drug post-approval study requirements. As described below, the growing reliance on RWD to assess pharmaceutical use, safety and effectiveness, and use of new technologies in these analyses will influence the generation of RWE to support regulatory decision-making.

FDA's RWE Program for drugs and biological products involves multiple components: guidance development to assist developers interested in using RWD to develop RWE and to support Agency decisions; internal processes that involve senior leadership in the evaluation of RWE and promote shared learning and consistency in applying the Framework; demonstration projects with a focus on evaluating/improving data quality and use of RWD, advancing study design, and developing rigorous evaluation tools; and external engagement, including listening sessions, presentations, publications, and international collaborations. In addition, the seventh iteration of the Prescription Drug User Fees Act included new RWE-related provisions, including the Advancing RWE Program that enables early discussions with sponsors regarding RWE-based study proposals and greater transparency around the submission of RWE to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research. In related work, FDA has published guidance documents and/or discussion papers on digital health technologies and the use of artificial intelligence (AI).

These activities lay a foundation for expansion of the use of RWD in evidence generation, but continued growth of these efforts requires increased coordination, knowledge management, internal support (including training), external visibility, and external engagement.

II. Topics for Discussion at the Public Workshop

FDA supports the continued evolution of using RWD to generate RWE that can support pre- and post-market regulatory decision-making at FDA for drugs and biological products. Topics for this public workshop will focus on FDA's current activities around RWE, ongoing accomplishments and challenges, and future opportunities.

Advancing existing priorities and activities of the RWE Program remains a focus area, including promoting consistency in review processes of submissions that contain RWE, and leveraging the full potential of RWD as well as emerging technologies to inform the effectiveness and safety of drugs and biological products.

To help facilitate the future direction of the RWE Program, FDA seeks input on the following questions.

1. Regulators, sponsors, and other interested parties are gaining experience with RWE in regulatory submissions. What are critical issues that need to be addressed to further advance the use of RWE in regulatory decision-making for drugs and biological products?

2. To advance our understanding of RWE, FDA has funded various demonstration (research) projects on topics such as RWD sources, study designs, and specific ''tools.'' What research priorities, including emerging technologies and AI, should CDER consider supporting?

3. FDA has published RWD/RWE guidance documents focused on data considerations, study design, and regulatory considerations. What additional topics could be prioritized for consideration?

4. FDA has utilized various mechanisms (*e.g.,* public meetings, webinars, ''listening sessions'') to engage interested parties; the Agency has also facilitated discussions with international regulators. What are optimal communication and engagement strategies to interact with the external community regarding RWE?

III. Participating in the Public Workshop

Registration: To register for this hybrid public workshop, please visit the following website: *https://duke.is/6/y7t5*. Please register for either in-person or virtual attendance and provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in-person must register by December 6, 2024, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Luke Durocher at *luke.durocher@duke.edu* no later than December 6, 2024.

Streaming of the Public Workshop: This public workshop will also be available via Zoom webinar to virtual attendees who register at *https://duke.is/6/y7t5.* For more information about Zoom, please visit *https://support.zoom.us/hc/en-us/articles/206175806-Frequently-asked-questions.*

Notice of this workshop is given pursuant to 21 CFR 10.65.

Dated: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26297 Filed 11–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–2514]

Determination That NUPLAZID (Pimavanserin Tartrate) Tablet, Equivalent 17 Milligram Base, Was 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 NUPLAZID (pimavanserin tartrate) tablet, equivalent (EQ) 17 milligram (mg) base, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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