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

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.

NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, is the subject of NDA 207318, held by Acadia Pharmaceuticals, Inc., and initially approved on April 29, 2016. NUPLAZID is an atypical antipsychotic indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

In a letter dated January 8, 2019, Acadia Pharmaceuticals, Inc., notified FDA that NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Zydus Pharmaceuticals (USA), Inc., submitted a citizen petition dated May 22, 2024 (Docket No. FDA–2024–P–2514), under 21 CFR 10.30, requesting that the Agency determine whether NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, was 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 NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, 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 NUPLAZID (pimavanserin tartrate) oral tablet, EQ 17 mg base, 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: November 6, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26318 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–N–2275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Produce Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 13, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is Produce Regulatory Program Standards. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Produce Regulatory Program Standards

OMB Control Number 0910–NEW

This information collection helps establish and implement FDA's ''Produce Regulatory Program Standards.'' Section 1012 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399c) authorizes FDA to administer training and education programs for employees of State, local, Territorial, and Tribal food safety authorities relating to regulatory programs. Also, under section 205 of the FDA Safety Modernization Act (codified in 21 U.S.C. 2224), FDA, together with the Centers for Disease Control and Prevention is directed to enhance foodborne illness surveillance to improve the collection, analysis, reporting, and usefulness of data on foodborne illnesses. As part of this effort, we have initiated programs that include developing and instituting regulatory standards intended to reduce the risk of foodborne illness through coordinated efforts with our strategic partners. Regulatory program standards establish a uniform foundation for the design and management of State, local, Tribal, and Territorial programs that have the responsibility for regulating human and animal food. Partnering with other regulatory officials also helps maximize limited resources in