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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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21 CFR 10.30, requesting that the Agency determine whether NUPLAZID (pimavanserin tartrate) tablet, EQ 17 mg base, was withdrawn from sale for reasons of safety or effectiveness.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

administering FDA regulations pertaining to the manufacturing/processing, packing, or holding of food for consumption in the United States.

The Produce Regulatory Program Standards (PRPS) are the result of external collaboration and coordination with the Association of Food and Drug Officials (AFDO), the National Association of State Departments of Agriculture (NASDA), and state produce regulatory programs. FDA, NASDA, AFDO, and states worked collaboratively to develop the content of the PRPS. A copy of the standards and accompanying worksheets and forms is available in the **Federal Register** docket for this notice. We recommend that State and Territorial produce safety regulatory programs use these program standards as the framework to design and manage their produce safety regulatory programs. The states that assisted in the development of PRPS were representative of the 43 State and Territorial programs regulatory programs enrolled currently conducting produce safety inspections via funding from a cooperative agreement grant, ''The FDA's Cooperative Agreement Program for States and Territories to Implement a National Produce Safety Program, PAR–21–174,'' (this program also includes 4 programs which do not conduct inspections). For more information on this cooperative agreement, we invite you to visit our website at: *https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/fda-state-produce-safety-implementation-cooperative-agreement-program.*

The PRPS identifies and includes resource and training material for the following standards: regulatory foundations; training; inspection; product-specific illnesses, outbreaks and hazard response; compliance and enforcement; industry and community relations; program assessments; and product sampling and testing. We recommend using the worksheets and forms contained in the standards, however, alternate forms that are equivalent may be used. The educational worksheets and resource materials include recordkeeping and reporting activities that help FDA verify participation and successful completion of the respective requirements. In the first year of enrollment, information is used to conduct a baseline self-assessment to determine whether the materials meet the elements of each standard. In subsequent years, we use the information to conduct a comprehensive review and evaluate program effectiveness and participation. We modify the program standards based on the ongoing assessments as well as comments and informal feedback obtained from participants.

Description of Respondents: Respondents are State Departments of Agriculture or Health regulatory officials who enroll in the PRPS (State or Territorial governments). Currently we estimate 43 respondents to the information collection based on expected participation.

In the **Federal Register** of June 28, 2024 (89 FR 54009), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that did not pertain to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State or Territorial Governments; Maintenance of data records consistent with the PRPS	48	11	528	85.36	45,072

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 30, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26209 Filed 11–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Department of Health and Human Services is hereby giving notice that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) charter has been renewed.

DATES: The effective date of charter renewal is November 10, 2024.

FOR FURTHER INFORMATION CONTACT: Leticia Manning, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, 18N38A, Rockville, Maryland 20857; 301–443–8335; or *lmanning@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

The charter renewal for the ACHDNC was approved on October 29, 2024. The filing date is November 10, 2024. Renewal of the ACHDNC charter