DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2275]

Agency Information Collection Activities; Proposed Collection; Comment Request; Produce Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on collections of information associated with our Produce Regulatory Program Standards (PRPS).

DATES: Either electronic or written comments on the collection of information must be submitted by August 27, 2024.

ADDRESSES: 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 August 27, 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.

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–2275 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Produce Regulatory Program Standards.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State or Territorial Governments; Development and reporting of data consistent with PRPS	43	11	473	88	41,624

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

To demonstrate conformance with the standards prior to and after enrollment in the grant program, State and Territorial governments participating in the PRPS (respondents) will submit comprehensive program assessments and evaluations to their technical advisors at FDA using a dedicated email. The information required for these submissions is outlined in the provided worksheets. Additionally, the PRPS requires ongoing documentation to verify conformance. We estimate, based on the implementation of other standards programs and informal consultation with the affected State and Territorial governments, that the information collection activities will average 968 hours annually for each of the 43 participants, for a total of 41,624 hours.

Dated: June 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14329 Filed 6–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0789]

Diversity Action Plans To Improve Enrollment of Participants From Underrepresented Populations in Clinical Studies; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is