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

announcing the availability of a draft guidance for industry entitled ''Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.'' FDA is issuing this draft guidance as mandated under the Food and Drug Omnibus Reform Act of 2022 (FDORA) which requires that FDA update or issue guidance relating to the format and content of Diversity Action Plans required by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by FDORA. This guidance describes the format and content of Diversity Action Plans, including the timing and process for submitting such plans by application or notification type. In addition, this draft guidance describes the criteria and process by which FDA will evaluate sponsors' requests for waivers from the FD&C Act. Because FDA is required by statute to specify the form and manner for the submission of Diversity Action Plans in guidance, insofar as this draft guidance specifies the form and manner for submission of Diversity Action Plans, when this guidance is finalized, it will have binding effect.

DATES: Submit either electronic or written comments on the draft guidance by September 26, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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–2021–D–0789 for ''Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; or Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Fashoyin-Aje, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0205; Tamy Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1125; or James Myers, Office of Communication, Outreach and Development, Center of Biologics Evaluation and Research, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Josh Chetta, Center for Devices and Radiological Health, Bldg. 66, Rm. 5554, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4910, *CDRHClinicalEvidence@fda.hhs.gov.*

For PRA comments: 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled

''Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies.'' FDA is issuing this guidance as mandated under section 3602 of FDORA, which requires that FDA update or issue guidance relating to the format and content of diversity action plans required by sections 505(z) and 520(g) of the FD&C Act (21 U.S.C. 355(z) and 360j(g) as amended by section 3601 of FDORA. This draft guidance describes the form, content, and manner of diversity action plans, the applicable medical products, and clinical studies for which a diversity action plan is required, the timing and process for submitting diversity action plans, and the criteria and process by which FDA will evaluate sponsors' requests for waivers from the requirement to submit a Diversity Action Plan. This draft guidance replaces the draft guidance for industry entitled ''Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials,'' published April 14, 2022 (87 FR 22211). The 2022 draft guidance, which issued prior to FDORA becoming law on December 29, 2022, provided recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan to enroll representative numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

Clinical studies characterize the safety and effectiveness of medical products intended for the prevention, treatment, or diagnosis of many conditions or diseases. Some populations in the United States are frequently underrepresented in biomedical research including in clinical studies, even when they have a disproportionate burden for certain conditions or diseases relative to their proportional representation in the general population. There are myriad reasons for this, including but not limited to assumptions regarding the feasibility of enrolling a population in a clinical study that is representative of the intended use population and the impact on study timelines, and the lack of the prospective development and implementation of a strategy that helps ensure enrollment and retention of a clinical study population representative of the intended use population.

Consistent with section 3602(a) of FDORA, this draft guidance primarily focuses on Diversity Action Plans for the enrollment and retention of a clinically relevant study population, to help ensure adequate representativeness of study participants that reflect different age groups, sexes, and racial and ethnic demographic characteristics. However, FDA recognizes the broader issues regarding health disparities and differential access to health care and clinical studies that may occur based on other factors, including but not limited to, geographic location, gender identity, sexual orientation, socioeconomic status, physical and mental disabilities, pregnancy status, lactation status, and comorbidity, and encourages sponsors to consider such additional factors when developing Diversity Action Plans. We welcome comments on how sponsors could effectively consider such additional factors, as appropriate, to broaden their Diversity Action Plans to include all clinically relevant populations. This draft guidance is one of many efforts by FDA to help address the participation of underrepresented populations to help ensure that clinical trials relating to FDA regulated products appropriately test the product against a representative sample of the product's intended use population.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. See 21 CFR 10.115(d). Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

An exception to that framework derives from the requirement in section 3601 of FDORA for FDA to specify in guidance the form and manner for the submission of Diversity Action Plans. Accordingly, insofar as Section VII of this document specifies the form and manner for submission of a Diversity Action Plan, it will have binding effect, once this guidance is finalized, as indicated by the use of the words, *must, shall,* or *required.*

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This draft guidance contains proposed collections of information. ''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 publish a 60-day notice in the **Federal Register** soliciting public comment on each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA will publish a 60-day notice on the proposed collections of information in this draft guidance in a separate issue of the **Federal Register**.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 25, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–14284 Filed 6–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): National Institute for Mental Health Strategic Plan Evaluation.

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Mental Health (NIMH), National Institutes of Health (NIH) is soliciting feedback on its current Strategic Plan for Research to inform the development of future strategic plans.

DATES: Comments must be received on or before (11:59:59 p.m. ET) on July 24, 2024 to ensure consideration.

ADDRESSES: Responses to this RFI must be submitted electronically using the web-based form at: *https://rfi.grants.nih.gov/?s=662fcf74748dc0f159063c02.*

FOR FURTHER INFORMATION CONTACT: Eliza Jacobs-Brichford, Ph.D., Science Policy and Evaluation Branch, Office of Science Policy, Planning, and Communications (OSPPC), National Institute of Mental Health, 6001 Executive Boulevard, MSC 9663, Telephone: 1–866–615–6464 (toll-free), 1–301–443–8431 (TTY), 1–866–415–8051 (TTY toll-free), Fax: 1–301–443–4279, Email: *NIMHStratPlan@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: