Dated: October 19, 2023.

Alison Barkoff,

Senior official performing the duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023–23563 Filed 10–24–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Standardized Reporting Forms for Food and Drug Administration Federally Funded Public Health Projects and Agreements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 November 24, 2023.

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 OMB control number for this information collection is 0910–0909. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Standardized Reporting Forms for FDA Federally Funded Public Health Projects

OMB Control Number 0910–0909—Revision

This information collection supports federally funded public health projects administered by FDA. As part of FDA's efforts to protect the public health, we work collaboratively with State partners to enhance oversight of FDA-regulated products. Consistent with applicable regulations, we collect information related to an awardee's progress in completing agreed-upon performance metrics.

To increase our efficiency in evaluating program effectiveness and return-on-investment (ROI)/return-on-value (ROV) for the federally funded projects that we administer, we developed and established the use of digital forms under a pilot project information collection that contain tailored, standardized questions to capture data elements necessary to measure/track ROI/ROV, best practices, and program effectiveness. Forms are submitted by email and aggregated into dynamic reports by program for FDA evaluators allowing for quick comparison of program data between report periods and comparable metrics to evaluate program success or lack of performance in a timely manner. The pilot project confirmed that the use of standardized forms will reduce the time required by awardees in completing and submitting data collection reports. Additional findings include: a drastic increase in data quality, a significant reduction in the number of follow-ups needed to request additional information or clarify responses, and the ability to aggregate data quickly into a useable format for programmatic review and respond effectively to requests for program performance data. Coupled with positive feedback from FDA data users and external partners received during the pilot project, we considered the pilot phase a success and plans to continue use of tailored forms for program performance metrics including ROI/ROV data for its current and new funded public health projects moving forward.

Respondents complete an initial report and progress/performance reports which include data fields to identify the award project and contact person and directs specific questions to respondents regarding project and progress updates. As the public, partnering awardees, and FDA data users provide feedback through various opportunities, we will revise the reports tailoring for project specificity and purpose, to include, but not limited to, improvements in metrics analysis, question clarity, and formatting and design, such as drop-down menu selections and potential common response indicators. This method will ensure a continuation of the reduced time for respondents and allow us to more quickly process information and determine impacts at the Agency level as observed during the pilot. As information will be requested of actively funded projects, it still may become necessary to request additional information for a particular project to complete the performance evaluation(s) in a timely manner. To ensure data is sufficient, on a case-by-case basis, FDA anticipates a need for follow-up questionnaire(s) to supplement the progress reports and as instruments of collection are developed and fine-tuned through this effort. We do not have any specific adjustments or revisions to the approved forms at this time, other than the inclusion of PRA statements. Due to the evolving nature of public health issues, non-substantive modifications may be made to the forms during the 3-year approval period of this information collection. Prior to implementation, such modifications will be submitted to OMB for approval, and they will be made available for public review and comment during the standard information collection extension/revision approval process.

In the **Federal Register** of July 29, 2021 (86 FR 40853), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received. Subsequent to the close of the 60-day notice public comment period, additional comments were received from internal and external stakeholders through our solicitation of feedback external to the PRA public comment opportunity. Upon our review, these comments were generally supportive of the piloted forms, and many contained suggestions for additional technical improvements. At the same time, none of the comments suggested any change to our estimated burden and we have therefore retained those currently submitted. While we are not making changes to the forms with this submission, we plan to implement changes based on the feedback received as part of the continuous improvement process for the information collection over the next few years.

Description of Respondents: Respondents to the information collection are State, local, Tribal and Territorial governments who are recipients of FDA-funded projects who submit required information to FDA.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Awardee activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Report; Update Reports; Supplement Reports (if applicable).	330	3.303	1,090	28.17 hours ..... (28 hours and 10 minutes)	30,700

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

We estimate that 330 respondents will participate in FDA funded projects and agreements annually and will submit 2 to 4 reports within a single yearlong budget period (Table 1). To ensure adequate reporting will be achieved over the course of these projects, the option for a supplement report is included in the estimated reporting burden; however, the need for these reports will be determined on a case-by-case basis with the FDA project manager. The estimated burden for each of the individual reporting activities was calculated based on the annual number of submissions and distributed among respondents.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Awardee activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Initial Report, Updated Reports, or Supplement Reports (if applicable).	330	3.303	1,090	0.5 hours ..... (30 minutes)	545

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

Recordkeeping activities include storing and maintaining records related to submitting a request to participate in the project and compiling reports. Respondents should use current record retention capabilities for electronic or paper storage to achieve these activities. We assume it will take 0.5 hour/year to ensure the documents related to submitting a request to participate in the program are retained properly according to their existing recordkeeping policies, but no less than 3 years, as recommended by FDA (Table 2). The estimated burden for each of the individual reporting activities was calculated based on the annual number of submissions and distributed among respondents.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Awardee-entity activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Coordination with partnering entities related to Initial Report, Update Reports, and Supplement Report (if applicable).	200	7	1,400	8	11,200

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

For those funded projects that involve a participant composed of partnering entities in the program, FDA is taking into consideration the time that partnering entities will spend coordinating with each other. We estimate that 200 respondents will work with their respective partnering entities and the average number of partnering entities will be 2. We assume each respondent will spend 8 hours coordinating with each partnering entity on each response for an estimated 7 responses or reports each (Table 3). The estimated burden for each of the individual reporting activities was calculated based on the annual number of submissions and distributed among respondents.

We are requesting OMB approval for conclusion of the pilot project and continued use of the forms for programmatic data collection needs. There are no adjustments or revisions to the estimated burden. However, this request results in an adjustment decrease in the number of responses, to correct data-entry errors in the database related to the previous submission to OMB.

Dated: October 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23560 Filed 10–24–23; 8:45 am]

BILLING CODE 4164–01–P