DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food 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: Fax written comments on the collection of information by September 9, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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.

Manufactured Food Regulatory Program Standards

OMB Control Number 0910–0601—Extension

In the **Federal Register** of July 20, 2006 (71 FR 41221), FDA announced the availability of a document entitled ''Manufactured Food Regulatory Program Standards.'' These program standards are the framework that States should use to design and manage their manufactured food programs. There are 43 State programs enrolled, which receive an average of $230,000 (maximum of $300,000) each year for a period of 5 years from the year they first enroll, provided there is significant conformance with and/or maintenance of the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if it meets the elements of each standard. FDA suggests that the State program use the worksheets and forms contained in the draft program standards; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifies records required for each standard. The information contained in the documents must be current and fit for use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met, (2) improvements needed to meet the program element or documentation requirement of the standard, and (3) projected completion dates for each task.

In the **Federal Register** of April 17, 2019 (84 FR 16020), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State Departments of Agriculture or Health	43	1	43	569	24,467

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
State Departments of Agriculture or Health	43	10	430	40	17,200

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

One additional State has enrolled in the program since 2016. The total estimated burden of this collection has increased to 41,667 hours among 43 respondents, from a previous total of 15,792 hours among 42 respondents. This increase is due to a change in the self-reported response times provided by the respondents. Because this is a long-term program, we believe this change is the result of more precise documentation by participating agencies as they have grown more experienced over time.

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16937 Filed 8–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2973]

Fabry Disease: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.