4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0115]

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North., 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 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 draft document entitled "Manufactured Food Regulatory Program Standards (MFRPS)." These program standards have since been finalized and updated multiple times. The current standards are the framework that States should use to design and manage their manufactured food programs. The current version expires on September 30, 2016, and FDA is proposing to update and submit for issuance with a new expiration date. The current and proposed versions of the standards are available at the docket number identified in brackets at the heading of this document. Persons with access to the Internet may submit email requests for a single copy of the draft manufactured food standards to OP-ORA@fda.hhs.gov. There are 42 State programs enrolled, in which each State may receive up to $300,000 each year for a period of 5 years provided there is significant conformance with 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. The State program should 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 improvement plan that includes the following: (1) The individual program element or 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 February 12, 2016 (81 FR 7544), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments. However, these comments did not address the information collection.

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

Table 1.--Estimated Annual Reporting Burden[1]

Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Departments of Agriculture or Health	42	1	42	376	15,792

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

The burden has been calculated as 376 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will change as accounted for in the continuing improvement and self-sufficiency of the program.

Dated: August 8, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy,

Planning, Legislation and Analysis.

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