4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0920]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

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 0910-0751. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, 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.

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food--21 CFR Part 117

OMB Control Number 0910-0751--Extension

This information collection supports FDA regulations. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Specifically, section 418 of the FD&C Act (21 U.S.C. 350g) sets forth requirements for hazard analysis and risk-based preventive controls for facilities that produce food for human consumption. To implement these provisions, regulations were codified under 21 CFR part 117--Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food. The regulations establish requirements for a written food safety plan; hazard analysis preventive controls; monitoring; corrective actions and corrections; verification; supply-chain program; recall plan; and associated records, and became effective November 16, 2015. Currently, we continue to evaluate burden associated with the information collection requirements; however, for purposes of extending the information collection, we retain the currently approved figures as shown in the tables below.

In the *Federal Register* of June 1, 2018 (83 FR 25466), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received stating that our estimate of burden associated with creating a food safety plan was too low and suggested a much higher figure. We appreciate this comment. However, because the annual burden is based on an industry average and because we continue to evaluate this relatively new collection, we are not adjusting our current estimate. At the same time, we continue to invite comment so that we might better refine our estimates for all elements of the collection.

Our estimate of the burden for the information collection is as follows:

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

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
117.201(e); qualified facility	37,134	0.5	18,567	0.5 (30 minutes)	9,284

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
117.126(c) and 117.170(d); food safety plan and reanalysis	46,685	1	46,685	110	5,135,350
117.136; assurance records	16,285	1	16,285	0.25 (15 minutes)	4,071
117.145(c); monitoring records	8,143	730	5,944,390	0.05 (3 minutes)	297,220
117.150(d); corrective actions and corrections records	16,285	2	32,570	1	32,570
117.155(b); verification records	8,143	244	1,986,892	0.05 (3 minutes)	99,345
117.160; validation records	3,677	6	22,062	0.25 (15 minutes)	5,515
117.475(c)(7)-(9); supplier records	16,285	10	162,850	4	651,400
117.180(d); training records for preventive controls qualified individual	46,685	1	46,685	0.25 (15 minutes)	11,671

Total					6,237,142

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

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
117.201(e); disclosure of food manufacturing facility address	37,134	1	37,134	0.25 (15 minutes)	9,284

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

As stated previously, we retain the currently approved burden for the information collection. These figures are based on our regulatory impact analysis in support of the final rule on preventive controls for human food, which published in the *Federal Register* of September 17, 2015 (80 FR 55908). Using Agency data, we estimated the number of food facilities that we believe are subject to the regulations. We base our estimate of the time necessary for the individual reporting, recordkeeping, and third-party disclosure activities on our experience with similar information collections.

Dated: September 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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