4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1164]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Qualified Facility Attestation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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: 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-NEW and title "Qualified Facility Attestation." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Qualified Facility Attestation

OMB Control Number 0910-NEW

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) enables FDA to better protect 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.

Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 418 (21 U.S.C. 350g) with requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans or animals. We have established regulations to implement these requirements primarily within subparts C and G, with associated requirements in subparts A, D, E, and F, of the rule entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (Preventive Controls for Human Food Rule) (21 CFR part 117) and primarily within subparts C and E, with associated requirements in subparts A, D, and F, of the rule entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (Preventive Controls for Animal Food Rule) (21 CFR part 507). A business that meets the definition of a "qualified facility" (see 21 CFR 117.3 or 21 CFR 507.3) is subject to modified requirements in § 117.201 of the Preventive Controls for Human Food Rule or in § 507.7 of the

Preventive Controls for Animal Food Rule. These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility.

Section 418(*l*)(2)(B)(ii) of the FD&C Act directs FDA to issue guidance on the documents a business is required to submit to FDA to show its status as a qualified facility. FDA issued a draft guidance for industry entitled, "Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Guidance for Industry." This draft guidance explains FDA's current thinking on how to determine whether a business is a qualified facility, and describes FDA procedures regarding the submission of attestations as established under both the Preventive Controls for Human Food Rule and the Preventive Controls for Animal Food Rule. FDA has developed proposed Forms FDA 3942a and FDA 3942b for use by a business in reporting its status as a "qualified facility" under the applicable regulations.

Description of Respondents: Respondents to the collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States, are required to register with FDA, and attest that a facility is a "qualified facility" under applicable FDA regulations.

In the *Federal Register* of May 16, 2016 (81 FR 30219), FDA published a 60-day notice requesting public comment on the proposed collection of information. One individual submitted several comments.

(Comment 1) One comment suggests that Forms FDA 3942a and FDA 3942b could be organized differently to help respondents. Specifically, the suggestion offered that the forms themselves should follow the submission type order as provided in section 2 of both forms so that the "Status Change" section is at the end of each form.

(Response) FDA agrees and will reorganize Forms FDA 3942a and FDA 3942b so that the "Status Change" section will now be section 6.

(Comment 2) One comment recommends changing the term "Biennial Submission" to "Biennial (Renewal) Submission" or in some way to indicate that biennial submission happens in the years after the "Initial Submission."

(Response) FDA agrees and will change "Biennial Submission" to "Biennial (Renewal) Submission" for both forms.

(Comment 3) One comment suggests that any revisions applied to either the forms or instructions should be consistent between all the documents.

(Response) FDA agrees and will make sure that revisions to the forms and instructions are consistent.

(Comment 4) One comment suggests that, for clarity, the instructions direct respondents to the guidance for additional reference.

(Response) FDA agrees and will include a reference to the guidance document in each section of the instruction document.

(Comment 5) One comment suggests that, for clarity, Question II.A.1 (and III.A. 1) of the guidance should advise respondents that the definition for "very small business" is forthcoming in the next question.

(Response) FDA agrees, and for clarity, will revise the final guidance to indicate that the definition for "very small business" is provided in the next question in the guidance.

(Comment 6) One comment suggests that Question II.A. 2 (and III.A.2) in the guidance should provide clarity as to the two options for meeting the qualified facility definition.

(Response) FDA agrees and will revise the final guidance to provide clarity as to the two options for meeting the qualified facility definition.

(Comment 7) One comment suggests that the guidance should provide more details about what other documentation FDA would accept as to support the first and second attestation options.

(Response) FDA agrees and will provide more details about the types of documentation FDA would accept to support the first attestation option. FDA will also include a list of examples of documents that FDA would accept to support the second attestation option consistent with the preamble discussions for §§ 117.201(a)(2)(ii) and 507.7(a)(2)(ii).

(Comment 8) One comment suggests that Question II.C.6 (and III.C.6) of the guidance oversimplifies the definition of farm and should clarify that farms that satisfy FDA's definition of "farm" need not submit Form FDA 3942a.

(Response) FDA agrees and will revise our responses to clarify that farms that satisfy FDA's definition of "farm" need not submit Form FDA 3942a or Form FDA 3942b.

(Comment 9) One comment suggests that Question II.C.7 (and III.C 7) of the guidance related to farm mixed-type facilities is missing certain information to assist farm mixed-type facilities to determine their level of coverage and compliance under regulations.

(Response) FDA agrees and will revise our response to provide greater clarity for farm mixed-type facilities to determine their level of coverage and compliance under the regulations.

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

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

Guidance Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Section II; Human Food	3942a	37,134	.5	18,567	.5 (30 minutes)	9,284
Section III; Animal Food	3942b	1,120	.5	560	.5 (30 minutes)	280

Guidance Section	FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Total						9,564

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

Consistent with the estimates found in our Preventive Controls for Human Food Rule, we estimate that approximately 37,134 human food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 18,567 responses and 9,284 burden hours associated with this information collection element.

Similarly, and consistent with the estimates found in our Preventive Controls for Animal Food Rule, we estimate that approximately 1,120 animal food facilities will each spend approximately 30 minutes (0.5 hour) reporting their status as a qualified facility to FDA every 2 years. Thus, dividing this figure by two to determine the annual burden, we estimate there will be 560 responses and 280 burden hours associated with this information collection element.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910-0751. The collections of information in 21 CFR part 507 have been approved under OMB control number 0910-0789.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-12615 Filed: 6/11/2018 8:45 am; Publication Date: 6/12/2018]