4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2013-N-0065]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities

**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 0910-0502. 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.

Registration of Food Facilities

OMB Control Number 0910-0502--Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), which, among other things, requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 to 1.235 of our regulations (21 CFR 1.230 to 1.235) set forth the requirements for the registration of food facilities. Information provided to us under these regulations helps us to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments.

Advance notice of imported food allows FDA, with the support of the Bureau of Customs and Border Protection, to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, we may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

To assist respondents of the information collection we developed the following forms. Each facility that manufactures, processes, packs, or holds food for human or animal

consumption in the United States must register with FDA using Form FDA 3537 entitled "Food Facility Registration" (§ 1.231), unless exempt under 21 CFR 1.226 from the requirement to register. To cancel a registration, respondents must use Form FDA 3537a entitled "Cancellation of Food Facility Registration" (§ 1.235). The terms "Form FDA 3537" and "Form FDA 3537a" refer to both the paper version of each form and the electronic system known as the Food Facility Registration Module, which is available at https://www.access.fda.gov. Beginning in January 2020, registrations, updates, and cancellations will be required to be submitted electronically. Domestic facilities are required to register whether or not food from the facility enters interstate commerce. Foreign facilities that manufacture, process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility outside the United States. However, if the further manufacturing/processing conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature, the former facility is required to register.

In addition to the initial registration requirements, a facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture, process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

Registration is one of several tools under the Bioterrorism Act that enables us to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or other food-related emergency. Further, in the event of an outbreak of foodborne illness, the information provided helps us determine the source and cause of the event and enables us to quickly notify food facilities that might be affected by an outbreak, terrorist attack, or other

emergency. Finally, the registration requirements enable us to quickly identify and remove from commerce an article of food for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.

*Description of Respondents*: Respondents to this 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.

In the *Federal Register* of April 19, 2019 (84 FR 16519), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the information collection.

We estimate the burden of this collection of information as follows:

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

| Activity; 21 CFR Section | FDA Form No.[2] | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|---|---|---|---|---|---|---|
| New domestic facility registration; 1.230-1.233 | 3537 | 9,795 | 1 | 9,795 | 2.7 | 26,447 |
| New foreign facility registration; 1.230-1.233 | 3537 | 13,697 | 1 | 13,697 | 8.7 | 119,164 |
| Updates; 1.234 | 3537 | 53,836 | 1 | 53,836 | 1.2 | 64,603 |
| Cancellations; 1.235 | 3537a | 6,390 | 1 | 6,390 | 1 | 6,390 |
| Biennial renewals; 1.235 | 3537 | 97,883 | 1 | 97,883 | 0.38 (23 minutes) | 37,196 |
| 3rd party registration verification | 3537 | 41,256 | 1 | 41,256 | 0.25 (15 minutes) | 10,314 |
| U.S. Agent verification | 3537 | 57,070 | 1 | 57,070 | 0.25 (15 minutes) | 14,268 |
| Total | | | | | | 278,382 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Forms FDA 3537 and FDA 3537a refer to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at https://www.access.fda.gov.

These burden figures are based on currently available data and reflect an overall decrease to the information collection by 174,395 and 31,370 hours. The decrease results from the realization of

burden associated with implementing measures on newly established electronic registration requirements.

Dated: July 17, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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