these methods of communication might be used when there is a foodborne illness outbreak, food recall, or other situation requiring expedited FDA food, dietary supplement, cosmetics, or animal food or feed communications. So that FDA may better protect the public health, the Agency needs quick turnaround information to help ensure its messaging has reached the target audience, has been effective, and, if needed, to update its communications during these events.

FDA will only submit individual collections for approval under this generic clearance if they meet the following conditions:
- The collections are voluntary;
- The collections are low burden for participants (based on considerations of total burden hours, total number of participants, or burden hours per participant) and are low cost for both

<table>
<thead>
<tr>
<th>Survey type</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden hours per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretest survey screener</td>
<td>750</td>
<td>1</td>
<td>750</td>
<td>0.083 (5 minutes)</td>
<td>38</td>
</tr>
<tr>
<td>Pretest survey</td>
<td>150</td>
<td>1</td>
<td>150</td>
<td>0.25 (15 minutes)</td>
<td>38</td>
</tr>
<tr>
<td>Self-Administered Surveys—Study Screener</td>
<td>75,000</td>
<td>1</td>
<td>75,000</td>
<td>0.083 (5 minutes)</td>
<td>6,225</td>
</tr>
<tr>
<td>Self-Administered Surveys</td>
<td>15,000</td>
<td>1</td>
<td>15,000</td>
<td>0.25 (15 minutes)</td>
<td>3,750</td>
</tr>
<tr>
<td>Pretest survey screener</td>
<td>60</td>
<td>1</td>
<td>60</td>
<td>1.5 (90 minutes)</td>
<td>90</td>
</tr>
<tr>
<td>Focus Group/Small Group, Cognitive Groups Screener</td>
<td>180</td>
<td>1</td>
<td>180</td>
<td>0.083 (5 minutes)</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10,881.25</td>
</tr>
</tbody>
</table>

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

This is a new collection of information whose total estimated annual burden is 10,881.25 hours. Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The number of participants to be included in each new individual survey will vary, depending on the nature of the compliance efforts and the target audience.

Dated: July 16, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019–15623 Filed 7–22–19; 8:45 am]
BILLING CODE 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.

For example, collections that collect PII to provide remuneration for participants of focus groups, in-depth interviews, and cognitive laboratory studies will be submitted under this request. All privacy act requirements will be met.

As defined in OMB and Agency Information Quality Guidelines, “influential” means that “an agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions.”
**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 August 22, 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 0910–0502. 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, PRAffa@ 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 are also 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>
<thead>
<tr>
<th>Activity</th>
<th>FDA form No. 2</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>New domestic facility registration; 1.230–1.233</td>
<td>3537</td>
<td>9,795</td>
<td>1</td>
<td>9,795</td>
<td>2.7</td>
<td>26,447</td>
</tr>
<tr>
<td>New foreign facility registration; 1.230–1.233</td>
<td>3537</td>
<td>13,697</td>
<td>1</td>
<td>13,697</td>
<td>8.7</td>
<td>119,164</td>
</tr>
<tr>
<td>Updates; 1.234</td>
<td>3537</td>
<td>53,836</td>
<td>1</td>
<td>53,836</td>
<td>1.2</td>
<td>64,603</td>
</tr>
<tr>
<td>Cancellations; 1.235</td>
<td>3537a</td>
<td>6,390</td>
<td>1</td>
<td>6,390</td>
<td>1</td>
<td>6,390</td>
</tr>
</tbody>
</table>
TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1—Continued

<table>
<thead>
<tr>
<th>Activity; 21 CFR section</th>
<th>FDA form No. 2</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biennial renewals; 1,235</td>
<td>3537</td>
<td>97,883</td>
<td>1</td>
<td>97,883</td>
<td>0.38 (23 minutes)</td>
<td>37,196</td>
</tr>
<tr>
<td>3rd party registration</td>
<td>3537</td>
<td>41,256</td>
<td>1</td>
<td>41,256</td>
<td>0.25 (15 minutes)</td>
<td>10,314</td>
</tr>
<tr>
<td>verification.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S. Agent verification</td>
<td>3537</td>
<td>57,070</td>
<td>1</td>
<td>57,070</td>
<td>0.25 (15 minutes)</td>
<td>14,268</td>
</tr>
</tbody>
</table>

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.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–153), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies 1 conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled “Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program” (81 FR 90186, December 14, 2016).

The FSMA FY 2020 third-party certification program user fee rate announced in this notice is effective on October 1, 2019, and will remain in effect through September 30, 2020.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2020

FDA must estimate its costs for each activity in order to establish fee rates for FY 2020. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2020

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered “hours worked” for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2020 cost. The FY 2020 FDA-wide average cost for payroll (salaries and benefits) is $160,885; non-payroll—including equipment, supplies, information technology, general and administrative overhead—is $92,828; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,888 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2020 average fully supported cost to $278,602 per FTE, excluding travel costs. FDA will use this base unit...