

unable to download an electronic copy of “Technical Performance Assessment of Quantitative Imaging in Premarket Device Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document

number 18017 to identify the guidance you are requesting.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the

Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

21 CFR Part; guidance; or FDA form	Topic	OMB Control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Device Exemption .....	0910–0332
812 .....	Investigational Device Exemption .....	0910–0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)”.	De Novo classification process .....	0910–0844
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions .....	0910–0756
800, 801, and 809 .....	Medical Device Labeling Regulations .....	0910–0485

Dated: April 16, 2019.  
**Lowell J. Schiller,**  
*Principal Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2013–N–0065]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of the Agency’s regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

**DATES:** Submit either electronic or written comments on the collection of information by June 18, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 18, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 18, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2013–N–0065 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**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, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### 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 (the 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity; 21 CFR section	FDA Form No. <sup>2</sup>	Number of respondents	Number 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

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

<sup>2</sup> 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: April 15, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0023]

#### Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application To Register Permanent Residence or Adjust Status

**AGENCY:** U.S. Citizenship and Immigration Services, Department of Homeland Security.

**ACTION:** 30-Day notice.

**SUMMARY:** The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

**DATES:** The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until May 20, 2019.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at [dhsdeskofficer@omb.eop.gov](mailto:dhsdeskofficer@omb.eop.gov). All submissions received must include the agency name and the OMB Control Number 1615–0023 in the subject line.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommès, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number; comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

**SUPPLEMENTARY INFORMATION:**

### Comments

The information collection notice was previously published in the **Federal Register** on February 1, 2019, at 84 FR 1193, allowing for a 60-day public comment period. USCIS did receive two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: <http://www.regulations.gov> and enter USCIS–2009–0020 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.