

Dated: December 30, 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-1423]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Imports and Electronic Import Entries

**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 renewal of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA import activities.

**DATES:** Submit either electronic or written comments on the collection of information by March 3, 2020.

**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 March 3, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 3, 2020. 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-1423 for "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment." 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.govinfo.gov/content/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. 3501-3521), 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.

**Imports and Electronic Import Entries**

*OMB Control Number 0910-0046—Revision*

This information collection supports Agency regulations in 21 CFR part 1, which govern FDA import activities. Specifically, the regulations prescribe the required data elements that respondents must submit when importing, or offering for import, an FDA-regulated article into the United States. The data elements allow FDA to continue to meet its responsibilities pertaining to current submission requirements established by the U.S. Customs and Border Protection (CBP) related to the submission of entry information in using its Automated Commercial Environment (ACE) system, or any CBP-authorized electronic data interchange (EDI) system. Respondents (ACE filers) submit important and useful information about FDA-regulated products being imported or offered for import into the United States so that we may effectively and efficiently review products and determine their admissibility. In addition, and as set forth in the regulations, certain product types are subject to additional data

elements (for example, 21 CFR 1.75 prescribes additional data elements for radiation-emitting products), as well as those data elements applicable to all products.

We are revising the information collection to provide for a weekly entry filing program (WEF). More detailed information on Foreign Trade Zones (FTZ)/WEF, is available at <https://www.fda.gov/industry/import-basics/foreign-trade-zones-weekly-entry-filing>. The WEF program, which is available for some FDA-regulated products, allows entry filers to file a single entry estimating the amount of merchandise anticipated to be removed from a FTZ and offered for U.S. consumption during a 7-day period. To participate, we recommend respondents who wish to file a weekly entry of FDA-regulated products with CBP, first request a preliminary assessment from FDA. As part of this assessment, we recommend submission of the following information:

- FDA Import Division(s) <sup>1</sup> with geographic oversight over the FTZ location;
- Identification of whether products are manufactured or stored in the FTZ;
- FTZ site/subzone number and address;
- Importer of Record (IOR) Facility Establishment Identifier (FEI), if known;
- Manufacturer FEI, if known; and
- Port of entry.

The division information is necessary so that we can appropriately route the submission within the Agency. Information on whether the product is stored or manufactured in the zone is necessary for FDA to determine the applicable admissibility requirements.

The FTZ and port information is necessary to ensure that basic requirements in 19 CFR 146 are met. The IOR and manufacturer FEI information is requested by FDA to expedite the admissibility review. Requests to participate in the WEF process are submitted to the FDA Import Division Office covering the intended port of entry.

We are also revising the information collection to include our Import Trade Auxiliary Communication System (ITACS), currently approved under OMB control number 0910-0842. The ITACS is used by the import trade community and was implemented to improve communication with FDA. By utilizing ITACS, respondents to the information collection have the ability to establish an account and electronically check the status of FDA-regulated entries and lines, submit entry documentation, submit the location of goods availability for those lines targeted for examination by the FDA, and check the estimated laboratory analysis completion dates for lines which have been sampled. For further information regarding ITACS, please visit our website at <https://www.fda.gov/industry/import-systems/itacs>.

*Description of Respondents:* Respondents to the information collection are domestic and foreign importers of FDA-regulated articles being imported or offered for import into the United States and entry filers who submit import entries on behalf of these importers.

We estimate the burden of the information collection as follows:

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

21 CFR part 1; subpart D	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Importers submission of data elements (preparing the required information).	85,480	10.05	859,074	0.05576 hours (3.346 minutes) .....	47,902
Entry filers (unique lines only) .....	3,419	12,196	41,698,124	0.04466 hours (2.68 minutes) .....	1,862,238
WEF participants .....	15	1	15	0.87 hours (52 minutes) .....	13.05
ITACS; creation of account .....	500	1	1	1 .....	250
<b>Total .....</b>			<b>42,557,214</b>		<b>1,910,403</b>

<sup>1</sup> There are no capital or operational and maintenance costs associated with the information collection.

An importer of record may be the owner or purchaser of the article being imported or offered for import, or a customs broker licensed by CBP under 19 U.S.C. 1641 who has been designated by the owner, purchaser, or consignee to file the import entry. There is only one importer of record per entry. We are

updating the number of responses and respondents since last OMB review of the information collection to reflect the best data available to the Agency from January 1, 2018, to December 31, 2018. Using these numbers, we update the number of importers to 85,480 and the number of entry filers to 3,419. We

retain our currently approved estimate with regard to the number of responses per respondent and time per response as representative of the industry average.

Persons wishing to file weekly entries of FDA regulated products are encouraged to provide the information identified so that FDA can conduct a

<sup>1</sup> Some FTZs are covered by multiple Import Divisions.

preliminary admissibility assessment of the associated products and firms. This submission typically contains the information FDA requests for multiple products (*i.e.*, the respondent wishes to file weekly entries for multiple products and submits the information for each product together). Generally, submissions involving multiple products are significantly less burdensome on a per-product basis. We estimate that the burden for each product in a WEF submission is approximately 52.5 minutes, for a total of 13.125 hours annually. Depending on the product and scale of submission, this estimated burden can fall to as low as 15 minutes per product. The reason why this burden can be significantly higher than an ACE submission is that the WEF submission is done manually, typically through a spreadsheet. Filers submitting in ACE typically use software that is developed to specifically automate and expedite the entry submission process and allows filers to automatically upload entry information. While the WEF submission includes an initial one-time submission burden, we expect reduced burden over a long term because filers can subsequently submit one entry covering multiple withdrawals from the FTZ in any given seven-day period.

Finally, since developing and implementing ITACS we believe that most respondents to the information collection have realized the one-time burden associated with creating an account and we have therefore adjusted our estimate downward by 2,500 hours. At the same time, we retain our estimate that 500 new accounts will be established annually for a total of 250 burden hours.

Cumulatively these changes and adjustments result in a reduction in annual responses by 40,112,208, and an increase in burden hours by 124,891. These changes and adjustments reflect the realization of one-time burden associated with conforming to new CBP electronic reporting requirements since last OMB approval of the information collection that we believe no longer applies, together with the consolidation of related information collection activities associated with ITACS.

Dated: December 30, 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-2016-N-3535]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Special Protocol Assessment; Guidance for Industry

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) 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 in the April 2018 guidance for industry entitled “Special Protocol Assessment” (Revision 1).

**DATES:** Submit either electronic or written comments on the collection of information by March 3, 2020.

**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 March 3, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 3, 2020. 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.

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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”).

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- 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. 2016-N-3535 for “Special Protocol Assessment; Guidance for Industry.” 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