TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interview Screening	4,800	1	4,800	.08 (5 minutes)	384
Individual In-Depth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	10,800	1	10,800	.08 (5 minutes)	864
Focus Groups/Small Group Discussion	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	.08 (5 minutes)	58
Observations	144	1	144	2	288
Total			20,464		7,394

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

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 collections we have conducted under this generic collection of information have informed and helped us better understand stakeholder perceptions, attitudes, motivations, and behaviors to help us improve our communications to them.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07441 Filed 4–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0895]

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, 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 information collection associated with our imports program.

DATES: Either electronic or written comments on the collection of information must be submitted by June 9, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–0895 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Imports and Electronic Import Entries.'' 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, 240–402–7500.

- 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, 240–402–7500.

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: 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 found in 21 CFR part 1, subparts D (21 CFR 1.70 through 1.81) and E (21 CFR 1.83 through 1.101), governing FDA import activities and related Agency guidance. 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. Review of the data elements allows 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 system. The regulations were recently revised through rulemaking to include data elements associated with import entries for veterinary devices (RIN 0910–AH66).

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 1.77 prescribes additional data elements for radiation-emitting products), as well as those data elements applicable to all products.

The information collection also includes our 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-zonesweekly-entry-filing.* The WEF program allows entry filers to file a single entry estimating the amount of merchandise anticipated to be removed from an 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 to first request a preliminary assessment from FDA. As part of the assessment, we also recommend submitting specific data elements, as discussed in the assessment. The information helps us appropriately route submissions within the Agency. Information on whether a 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 part 146 are met. The importer of record (IOR) and manufacturer FDA establishment identification number 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.

The information collection also includes our Import Trade Auxiliary Communication System (ITACS). 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 FDA, and check the estimated laboratory analysis completion dates for lines that have been sampled. For further information regarding ITACS, please visit our website at *https://www.fda.gov/industry/import-systems/itacs.*

The information collection also includes burden associated with the use of Form FDA 766 entitled ''Application for Authorization to Relabel or Recondition Non-compliant Articles'' as the collection instrument for 21 CFR 1.95. Form FDA 766 facilitates collection of information associated with certain general enforcement provisions for importing FDA-regulated articles into the United States. The form is available at *https://www.fda.gov/industry/actions-enforcement/reconditioning.*

Relatedly, we are revising the information collection to include burden associated with the use of proposed electronic Form FDA 5054 entitled ''New Inquiry Form—Import Compliance Branch.'' Currently, general drug import inquiries are submitted by email in random format. We have developed Form FDA 5054 with accompanying instructions to facilitate responding to drug import inquiries, as well as to track receipts and responses. We have designed the form to interface with current Agency IT systems for optimal utility.

Finally, the information collection includes burden associated with recommendations found in the procedural Agency guidance entitled ''Pre-Launch Activities Importation

Requests (PLAIR),'' (March 2022). Historically, when applicants with a pending new drug application, abbreviated new drug application, or Center for Drug Evaluation and Research-regulated biologics licensing application (information collection associated with these submissions is currently approved under OMB control number 0910–0001) sought to import unapproved finished dosage form drug products into the United States in preparation for market launch, we considered such requests, informally referred to as ''PLAIRs,'' on a case-by-case basis. Since implementing the PLAIR program in 2013, interest continues to increase, so we have developed a more formalized process as discussed in the guidance document. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pre-launch-activities-importation-requests-plair* and was issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment on Agency guidance documents at any time. The guidance document instructs that PLAIR submissions should be made using the applicant's letterhead and submitted by email to *CDER-OC-PLAIR@fda.hhs.gov* in a file compatible with Portable Document Format (PDF).

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 [1] [2]

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).	95,307	10.14	967,069	0.05576 (3.346 minutes)	53,924
Entry filers (unique lines only)	4,133	10,804	44,656,657	0.04466 (2.68 minutes)	1,994,336
WEF participants	10	1	10	0.87 (52 minutes)	9
ITACS; creation of new account	500	1	1	0.5 (30 minutes)	250
Form FDA 766 as required under 21 CFR 1.95	324	1	324	0.25 (15 minutes)	81
Form FDA 5054	1,000	1	1,000	.083 (5 minutes)	83
Submissions in accordance w/PLAIR	80	4	320	16	5,120
Total			45,625,381		2,053,803

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to reflect electronic submission data.

Table 1, rows 1 and 2, reflects annual average filing submissions through December 31, 2022. An IOR 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 IOR per entry.

As reflected in table 1, row 3, we estimate 10 respondents will submit WEFs. Persons wishing to file weekly entries of FDA-regulated products are encouraged to provide the information identified so that FDA can conduct a 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. Depending on the product and scale of submission, this estimated burden may fluctuate. 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 7-day period.

As reflected in table 1, row 4, we estimate that 500 new ITACS accounts will be created annually. Since developing and implementing ITACS, we have adjusted this estimate downward to reflect the transition from initial program interest to average annual maintenance-level numbers.

As reflected in table 1, row 5, we estimate the submission of 324 Forms FDA 766 in conjunction with FDA-regulated products. This figure is based on Agency import data and our experience with the information collection. We assume it takes respondents 15 minutes to complete and submit Form FDA 766. Although current instructions communicate that four copies be submitted (one copy to be returned to respondent), we plan to update the form to reduce this number.

Based on inquiries already received and processed by FDA, we anticipate 1,000 respondents will annually submit Form 5054 pertaining to general drug import information, as reflected in table 1, row 6.

As shown in table 1, row 7, we estimate 80 respondents to the PLAIR program annually, an increase of 10 since our last evaluation of the information collection. At the same time, we estimate one fewer submission per respondent to correspond with a decrease in submissions received by FDA.

Cumulatively these changes and adjustments result in an increase of 3,067,493 responses and 137,719 hours annually.

Dated: April 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07442 Filed 4–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–0047—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995,