Estimated Total Annual Burden Hours: 1,050.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 5106, Public Law 111–320, the Child Abuse Prevention and Treatment Act Reauthorization Act of 2010, and titles IV–B and IV–E of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–13677 Filed 6–27–23; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0895]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Imports and Electronic Import Entries

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: Submit written comments (including recommendations) on the collection of information by July 28, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0046. 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.

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). 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. 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 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.

In the **Federal Register** of April 10, 2023 (88 FR 21195) we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received suggesting FDA underestimated burden that might be attributable to transactional data entry and necessary preparation. We note that included in our estimate is the time we believe necessary for associated recordkeeping, and that we assume certain recordkeeping attendant to import activities is usual and customary. At the same time, we have increased our estimate associated with the preparation of line-item data to reflect this comment. Another comment suggested FDA invest in utility enhancements that might improve that Agency's electronic interface with importers' systems. We appreciate this comment and continue to make process improvements including upgrades in automated technology as our limited resources permit.

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	0.08 (5 minutes)	77,366
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		2,077,245

[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 161,161 hours annually.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13729 Filed 6–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2613]

Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.'' This guidance provides recommendations for presenting quantitative efficacy and risk information in DTC promotional labeling and advertisements for prescription human drug and biological products and prescription animal drugs and in DTC promotional labeling for over-the-counter (OTC) animal drugs (collectively, ''promotional communications''). FDA is issuing this guidance to describe the Agency's recommendations for how manufacturers, distributors, and packers (collectively, ''firms'') that include quantitative efficacy or risk information about their drugs in DTC promotional communications can make the language and presentation more consumer-friendly. This guidance finalizes the draft guidance of the same title issued in October 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on June 28, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2018–D–2613 for ''Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research,