

UNITED STATES FOOD & DRUG ADMINISTRATION

Imports; and Electronic Import Entries
21 CFR Part 1 – General Enforcement Regulations;
Subparts D and E

OMB Control No. 0910-0046 - Revision

SUPPORTING STATEMENT – Part A: Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations found in 21 CFR part 1; *General Enforcement Regulations*, pertaining to imports and electronic import entries; specifically 21 CFR part 1, subparts D and E (21 CFR §§ 1.70-1.101). Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) charges the Secretary of Health and Human Services (HHS), through the FDA, with the responsibility of assuring the safety of FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States. This responsibility is met through coordination and cooperation between FDA headquarters and field inspection personnel and the U.S. Customs and Border Protection (CBP) Service. Agency regulations prescribe 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 us to continue to meet our responsibilities pertaining to current submission requirements established by the U.S. 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, as well as agency regulations. The regulations were recently revised through rulemaking to include data elements associated with import entries for veterinary devices (RIN 0910-AH66).

The information collection includes the following elements:

- **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.

- **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>.
- 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>.
- 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.
- Burden associated with the agency guidance document 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 for download 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 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).

We therefore request OMB approval for the information collection provisions found in 21 CFR part 1, subparts D and E, the associated forms, and applicable guidance, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The respondents to this collection of information are importers of FDA-regulated products who are private businesses importing goods from foreign countries. The information collection is used to determine product compliance and admissibility. 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.

3. Use of Improved Information Technology and Burden Reduction

The information collection is effected through the submission of information and electronic interface between FDA systems and the ACE System utilized by CBP. We estimate 100% of respondents will utilize electronic means to provide the information. FDA has also developed ITACS, as discussed above, and other reporting and tracking systems to minimize burden on respondents and increase agency efficiencies in reviewing the necessary information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information provided by filers is voluntary and we do not believe it imposes any undue burden on small entities. If needed, filers can obtain assistance from their local FDA district, as well as from agency resources available on our website at www.fda.gov.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Information for this data collection is reported to FDA each time a shipment is imported into the United States by the respondent to allow FDA to either accept each line of the shipment, or indicate that product requires further FDA review. Also, under 19 CFR 163.4(a) filers are required to retain all entry documents for five years after the date of entry.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60 day notice soliciting public comment for the proposed collection of information in the Federal Register of April 10, 2023 (88 FR 21195). One comment was received suggesting FDA underestimated burden that might be attributable to transactional data entry and necessary preparation. Although we noted that our estimate included time we believe necessary for attendance recordkeeping, we adjusted our estimate for this activity upward in consideration of the comment.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality has been provided except as generally considered in review guidelines in 21 CFR 20.61.

11. Justification for Sensitive Questions

There were no questions asked of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a Annualized Hour Burden Estimate:

Table 1.--Estimated Annual Reporting Burden^{1,2}

| 21 CFR Part 1, Subpart D | No. of Respondents | No. 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.

12b. Annualized Cost Burden Estimate

The total estimated cost burden for this collection of information is based upon performing a similar position in the government as private industry. The cost to respondents is estimated to approach the hourly cost of a GS-10, step 5 worker, or \$31 per hour. Therefore, the cost associated with this collection is **\$ 59,398,604**.

| Type of Respondent | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|--------------------|--------------------|------------------|------------------------|
| Industry Analyst | 2,053,803 | \$31.00 | \$63,667,893 |

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We calculate annual costs to the Federal government to be \$38,750,000 to reflect the allocation of 155 FTE's, assuming a loaded cost of \$250,000 per employee.

15. Explanation for Program Changes or Adjustments

We are revising the information collection to add new forms for certain drug import activities. Also, we note an inadvertent error in our burden table denoting the number of new ITACS accounts created annually. Finally, in response to public comment, we adjusted our estimate as discussed in Q-8 above. Cumulatively these changes and adjustments result in an increase of 3,067,493 responses and 161,161 hours annually.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of the data is planned or anticipated, however general information regarding FDA import activities may be found at <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda>.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.