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 of our 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.

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.

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-zonesweekly-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 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 this assessment, we recommend submission of the following information:

- FDA Import Division(s) 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 part 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 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.

For operational efficiency we are including Form FDA 766 "*Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts*" (currently approved under OMB control number 0910-0025) as the collection instrument associated with 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 on the internet at https://www.fda.gov/industry/actions-enforcement/reconditioning.

Relatedly, we also are revising the information collection to include reference to agency guidance pertaining to importing drug products entitled "*Pre-Launch Activities Importation Requests* (PLAIR)." Historically, when applicants with a pending new drug application, abbreviated new drug application, or Center of 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 and we have therefore worked to develop a more formalized

process. To facilitate submissions and improve our own efficiencies, we developed the draft guidance. We intend to finalize the guidance document to further clarify our recommendations on what products are eligible for a PLAIR, what information should be included in a PLAIR submission, when and how a PLAIR can be submitted to FDA, and the circumstances under which the agency intends to grant a PLAIR. The draft guidance is available from our website at: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports and is being 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.

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.

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 and is driven by respondents who elect to import FDA-regulated products into the United States. Because of the very large number of FDA-regulated products imported to the U.S. each year, FDA cannot physically examine every FDA-regulated article. Therefore, it is essential that we receive reportable information.

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 information collection in the Federal Register of January 3, 2020 (85 FR 318). No comments were received.

   In addition, in the Federal Register of July 24, 2013 (78 FR 44572), we announced a draft guidance document discussing our PLAIR program, including an analysis under the PRA of the burden we estimate is attributable to the applicable information collection activity. No comments were received regarding the utility of the information collection or the burden estimates we ascribed.

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]

21 CFR Part 1, Subpart D	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. 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 mins.)	47,902
Entry filers (unique lines only)	3,419	12,196	41,698,124	0.04466 hours (2.68 mins.)	1,862,238
WEF participants	15	1	15	0.87 hours (52 mins.)	13.05
ITACS; creation of new account	500	1	1	0.5 (30 mins.)	250
Form FDA 766	324	1	324	0.25 (15 mins.)	81
Submissions in accordance w/PLAIR	70	5	350	16	5,600
Total			42,557,888		1,916,084

[1] There are no capital or operational and maintenance costs associated with the information collection.

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	1,916,084	$31.00	$59,398,604

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 estimate an annual cost to the Federal government of $38,750,000 to reflect the allocation of 155 FTE's, assuming a loaded cost of $250,000 per employee. This is based on previous formulations found in our impact analysis in support of recent rulemaking (0910-AH41) for which we have made no adjustment.

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes as well as adjustments. We have made a number of revisions to the collection to streamline agency operations. We are introducing a weekly entry filing program (WEF) for respondents; we are consolidating burden from related information collection activity (ITACS); and we are adding collection instruments. Specifically, Form FDA 766 associated with relabeling and reconditioning products under 21 CFR 1.95 is being added to the collection to align with the regulation; we currently account for this burden elsewhere (0910-0025). Also, we are adding agency guidance pertaining to the import of drug products covered by our PLAIR program. Finally, we are removing one-time burden associated with rulemaking (0910-AH41) that we believe has since been realized by respondents. Cumulatively, these changes and revisions result in 40,111,035 fewer annual responses and 130,572 less burden hours to the information collection.

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.