United States Food and Drug Administration
Imports; and Electronic Import Entries
OMB Control No. 0910-0046
RIN 0910-0910-AI64

SUPPORTING STATEMENT PART A

Terms of Clearance: None

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection request supports agency rulemaking. The legal authority for 21 CFR part 1 subpart D is derived sections 201, 701, 801, and 910 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 371, 381 and 387j, respectively).

Currently, this information collection accounts for the data elements collected in the Automated Commercial Environment (ACE) from importers regarding products regulated by the U.S. Food and Drug Administration the agency that are being imported or offered for import into the U.S., in accordance with 21 CFR part 1 subpart D as revised by the final rule entitled, "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment," (81 FR 85854; November 29, 2016) ("the ACE final rule").

The proposed rulemaking revises the ICR to account for the additional collections of information in FDA's proposed rule, "Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products". The rule proposes to require that the Affirmation of Compliance (code "TST" and the Tobacco Submission Tracking Number (STN)) for entries containing ENDS products that are imported or offered for import into the United States, which is now an optional submission, be a required submission via the ACE or any other electronic data interchange (EDI) system authorized by U.S. Customs and Border Protection (CBP).

Although primary responsibility for administering U.S. laws relating to imports is exercised by CBP, FDA is responsible for determining whether or not FDA-regulated articles are in compliance with the laws enforced by FDA and should be allowed to enter the U.S. The proposed rule and corresponding revision of this ICR would increase effective and efficient admissibility review by FDA, which will protect public health by allowing the agency to focus its limited resources on FDA-regulated products that may be associated with a greater public health risk.

When shipments of goods are being imported or offered for import into the United States they must be "entered" at one of the CBP ports. The term "import entry," or "entry," refers to the information or documentation for a shipment that a filer must submit in ACE. An import entry line (or "line") is each portion of an entry that is listed as a separate item on an entry submission. CBP requires importers to submit entry line information, such as the entry number, importer of record, country of origin, product description, etc., for all merchandise imported into the U.S. unless specifically exempt.

After the entry filer submits the entry information in ACE, CBP electronically transmits that information to FDA. Because CBP relays the information to FDA electronically, generally the entry filer only needs to submit the entry information once, provided the information is accurate.

2. Purpose and Use of the Information Collection

The proposed rule would revise subpart D of part 1 of 21 CFR chapter I (21 CFR part 1), added by a final rule issued by the Agency on November 29, 2016 (81 FR 85854), which established requirements for the electronic filing of certain data elements for FDA-regulated products in ACE, or any other EDI system authorized by CBP, at the time of entry. That final rule took effect on December 29, 2016.

The proposed rule would require, instead of allowing for optional submission, that the filer submit in ACE at the time of entry the Affirmation of Compliance, which consists of code "TST" and, the STN assigned by the Agency to the application for premarket review for an ENDS product under section 910 of the Federal Food, Drug and Cosmetic Act (FD&C Act). Submission of this information would help FDA to make admissibility determinations more effectively and efficiently for ENDS products being imported or offered for import by increasing the opportunity for issuing a release without manual review of these entries by FDA's import systems.

3. Use of Improved Information Technology and Burden Reduction

Based on previous usage, FDA estimates that at least 96% of respondents will use ACE to electronically submit the information collected by this ICR.

Automated systems and associated electronic data storage of data have also been of great value to FDA personnel responsible for planning and delegating imports work, e.g., determining what FDA-regulated products and quantities are arriving at which ports, from which manufacturers, and from what countries, etc., and what products to physically examine and sample. FDA expects the collection of information required by the proposed rule and the improved information technology capabilities of ACE to increase this value to FDA.

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 collections in this proposed rule will not have a significant economic impact on a substantial number of small entities. As discussed in the PRIA, only 0.6 percent of all import lines are tobacco products, as such we expect only a small proportion of all small entities in the wholesale trade and brokers industry would be affected by the rule.

6. Consequences of Collecting the Information Less Frequently

Respondents to this data collection are expected to respond occasionally – i.e., when imported shipments arrive or are due to arrive to the United States. Information must be submitted before or at the time goods arrive in the U.S. to enable FDA to determine if the product will be allowed to proceed into U.S. commerce immediately or should be held pending further FDA review.

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 for FDA to receive information about every FDA-regulated article being imported or offered for import into the United States so FDA may remotely and electronically review the information to strategically focus FDA's resources on which articles FDA should admit without further review, which articles

to detain without physical examination, and which articles to allocate further resources to, for example, by physically examining and/or sampling an article.

If the information were to be submitted on a less frequent basis, FDA could not adequately meet its statutory responsibilities to regulate imported products falling under FDA's jurisdiction, nor could it prevent those FDA-regulated products that potentially present a public health risk from entering the U.S. market. In turn, this lack of information could have an adverse effect on the American population, who is the final purchaser and consumer of these products.

This requested revision of the previously approved information collection request is vital since submission of this information would help FDA to make admissibility determinations more effectively and efficiently for ENDS products being imported or offered for import by increasing the opportunity for issuing a release without manual review of these entries by FDA's import systems. If FDA were not able to collect the FDA-specific data elements in ACE under the rule, FDA's ability to determine the risk level of imported FDA-regulated products would be severely hampered. Coupled with the data elements required by CBP and shared with FDA, the required data element in the rule are the key data/information that would most assist the Agency in making our initial admissibility determinations. Because receipt of this information would increase the opportunity for automated review for admissibility of an import entry, this rule would allow the Agency to focus our resources on ENDS products that have not received a marketing granted order and may be associated with a greater public health risk.

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

A respondent submits the information for this data collection in ACE at the time of filing entry each time the respondent imports or offers for import an FDA-regulated product to the U.S. This information is then electronically transmitted by CBP to FDA.

With regard to record retention, CBP regulation 19 CFR 163.4(a) requires filers to retain all entry documents for five years after the date of entry.

Although respondents may submit proprietary, trade secret, or other confidential information in response to this ICR, FDA and CBP have systems and procedures to protect the information's confidentiality in accordance with applicable law. FDA reviews the FDA-required information submitted in ACE and conducts filer evaluations to make certain that accurate information is being transmitted by filers.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the Federal Register of mm/dd/yyyy (Vol. No. FR page number)."

In developing the proposed rule and this associated collection of information, HHS/FDA consulted with CBP and the Department of the Treasury.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

The mandatory gathering and submission of the STN in this proposed rule ICR does not involve collecting personally identifiable information (PII) or other information of a personal nature.

However, as part of the submission into ACE PII is collected, in the context of the individuals' professional capacity. The PII is collected by the Customs and Border Protection (CBP). This proposed rule would require submission of the Tobacco Submission Tracking Number assigned by the Agency to the application for premarket review for an ENDS product of the importer of record in the (ACE), operated by CBP, at time of entry for entries containing Electronic Nicotine Delivery System (ENDS) products that are imported or offered for import into the United States. CBP transmits this data along with other PII related to the importer of record, to an automated FDA system for processing and making admissibility determinations on FDA-regulated products that are being imported or offered for import into the U.S. CBP transmits this information to FDA since Title 19 and 21 give FDA the authority to make determinations for admission of FDA-regulated products. PII transmitted to the FDA is maintained in a Privacy Act System of Records as described in DHS/CBP System of Records (SORN) DHS/CBP/001for Import Information System (IIS). CBP provides notice to the trade community on its website about the ACE system. CBP provides notice of the scope of information collected in ACE through notices and rulemakings in the Federal Register, information posted on the public CBP website, the IIS SORN, and the PIA. In addition, E.O. 13659 requires CBP to publicly post ACE modernization implementation plans and schedules.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Description of Respondents: Respondents to the information collection provisions of the proposed rule are Tobacco Product importers who offer products for importation that are a finished ENDS product or finished ENDS component or part product.

The proposed rule would add the Tobacco Submission Tracking Number assigned to the premarket application for an ENDS product under section 910 of the FD&C Act to the data elements required for entries containing FDA-regulated tobacco products in proposed § 1.79(b) that must be submitted in ACE at the time of entry. Currently, this is an optional submission in ACE for ENDS products. By requiring the Tobacco Submission Tracking Number to be submitted in ACE at the time of entry for finished ENDS products offered for import into the U.S., FDA will be able to determine the premarket review status of these products more effectively and efficiently, and thereby enforce the tobacco premarket requirements of Chapter IX of the FD&C Act.

FDA's burden estimates are based on data discussed in the Preliminary Regulatory Impact Analysis (PRIA). For the analysis of the information collection, we calculate the submission of the STN in the ACE system as initial first-year burden and subsequent recurring years. We anticipate these data retrieval and entry times to occur in the first year the rule becomes effective for all

products imported or offered for import as a requirement upon initial submission of import information for newly importing entities and products. In each subsequent year, any additional time spent preparing the required information would depend on the number of new products imported or offered for import. As discussed in the PRIA, we assessed the baseline procedure for verifying marketing status. Entries received without the optional STN data element trigger a manual review process to determine their premarket review status. By 2021, only one ENDS filer had voluntarily submitted a STN. For simplicity, we therefore assume that no filers are submitting this information at baseline. For each unique import filer-manufacturer-product import line covered by this proposed rule, if finalized, we assume time would be spent by an administrative worker on locating the sources of the data; preparing the required information for entering into ACE, including reaching out to manufacturers if necessary; logging into the system; entering the required information or updating the already existing information in that firm's internal database. Once this information is gathered and entered into the filer's internal databases, we foresee that it does not need to be gathered again for a subsequent shipment of the same product produced by the same manufacturer.

We anticipate these data retrieval and entry times to occur in the first year the rule becomes effective for all products imported or offered for import as a requirement upon initial submission of import information for newly importing entities and products. In each subsequent year, any additional time spent preparing the required information would depend on the number of new products imported or offered for import.

FDA estimates the burden of this collection of information as follows:

21 CFR 1.79(b)/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Gathering and Entering STN into Filer's Internal Database	177	60.825*	10,766*	0.033	355*

Table 1. – Estimated **First-Year** Reporting Burden

Table 1 displays the estimated first year reporting burden associated with gathering and entering the required STN for certain Tobacco Products into filer's internal database. Our burden estimates are consistent with estimates from Table 5 in the PRIA, which summarizes the number of import lines, import filers, and products expected to be affected by the rule. We identify unique products through unique combinations of manufacturer, product code, and import filer. Table 5 in the PRIA presents low and high estimates. For PRA purposes, we have utilized the midpoint of these low and high values. We estimate that 177 respondents (number of import filers) will submit 10,766 annual responses (number of unique import filer-manufacturer-product combinations) in the first year that the proposed rule is finalized. The 2016 ACE final rule (85 FR 46566) assumed that preparing data elements for the first time could range from a few seconds to several minutes, depending on the complexity and location of the information. We assume that importers have the required information readily available and that they will not need to contact manufacturers or other entities to obtain this data element. Likewise, we assume that importers would provide the necessary information to any brokers they hire to complete these tasks. Finally, we assume that this time includes quality checks to ensure the accuracy of the information submitted in ACE. Some of this verification may be manual verification by staff or automated messaging from ACE that identifies incorrect information. To calculate the average burden per response we utilized

assumptions in the 2016 ACE final rule, and we assume the time needed to locate, prepare, enter, and quality check the required information would range from one to three minutes per unique import filer-manufacturer-product. For PRA estimates we have used the midpoint of 2 minutes (0.033 hours) per response. Our total first year burden is estimated to be 355 hours.

21 CFR 1.79(b)/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Gathering and Entering STN into Filer's Internal Database	177	20.275	3,589 (rounded)	0.033	118

Table 2. – Estimated **First-Year** Reporting Burden: **ROCIS ENTRY**

Table 2, as instructed by HHS, displays the burden entered into ROCIS. The No. of Responses per Respondent, Total Annual Responses and Total Hours have been divided by three.

21 CFR 1.79(b)/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Gathering and Entering Submission Tracking Number into Filer's Internal Database	5	94	470	0.033	16

Table 3. – Estimated **ON-GOING** Reporting Burden

Table 3 displays the estimated subsequent years burden associated with gathering and entering STN into filer's internal database the required Submission Tracking Number for certain Tobacco Products. In each subsequent year after year one, any additional time spent preparing the required information would depend on the number of new products imported or offered for import. As with the estimate for first year burden, our estimates for subsequent year burden are based on the midpoint of low and high estimates from Table 5 in the PRIA. We estimate recurring burden by averaging years 2-3 based on a three-year OMB approval timeframe, which equaled to 5.25 respondents (number of import filers) and rounded to 5. For the number of annual responses, we used the average of years 2-3 which equaled to 470 annual responses (number of unique import filer manufacturer product combinations). We estimate the same estimate of 2 minutes (0.033 hours) per response as in Table 2, and our total recurring burden is estimated to be a rounded 16 hours.

Tables 2 and 3, when added together represents the burden entered into ROCIS resulting in 4,059 annual number of responses and 134 annual time burden.

12b. Annualized Cost Burden Estimate

As stated in 12a above, the analysis of the collection of information and its related burden on respondents for the PRIA incorporates the one-time and recurring burden related to importation of tobacco products. In accordance with the methodology used by the PRIA for this proposed rule, FDA is using a labor cost of $103.23 (= (128.40 + 138.12 + 43.16) / 3), which is the average for the wholesale trade industry between the cost for management, legal, and office and administrative support, and includes overhead costs and benefits. The total annualized cost burden estimate

under this ICR would be $36,646.65 in the first year (355 hours x $103.23 per hour) and $1,651.68 (16 hours x $103.23 per hour) in years 2-3 thereafter for a total of $38,298.33.

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

There are no capital costs or operating and maintenance costs associated with this collection of information

14. Annualized Cost to the Federal Government

The proposed rule, if finalized, would result in more effective and efficient admissibility review by FDA of those entry lines containing an ENDS product. It will also allow for more efficient identification and refusal of admission to noncompliant products that may be associated with a greater public health risk. Industry may also benefit from reduced verification time for admissibility determinations. We expect the federal government and industry to experience cost savings from more efficient and effective import review and enforcement. The estimated annualized costs range from $1,401 to $4,894 with an average of $3,148.

Including the existing costs reported in the last revision of this ICR we therefore, estima96te the cost to the government is estimated to be $38,753,148.

15. Explanation for Program Changes or Adjustments

This a revision to the current information collection. If this proposed rule is finalized, we estimate that Tobacco Product Importers gathering and submitting the required STN will increase the burden by 371 hours (355 first year burden hours + 16 burden hours for subsequent years). This revision, when added to current burden for 0910-0046 results in total burden of 45,629,939 responses and 2,053,937 hours. These totals include, as instructed by HHS, the ONE-TIME burden for the No. of Responses per Respondent, Total Annual Responses and Total Hours divided by three.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA is not seeking approval to not display the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.