

UNITED STATES FOOD & DRUG ADMINISTRATION

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

0910-0046
RIN 0910-AH66

SUPPORTING STATEMENT

Terms of Clearance: None.

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 from sections 536, 701, and 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360mm, 371, and 381, respectively), and sections 351, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 262, 264, and 271, respectively).

Currently, the information collection accounts for the data elements currently 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*”). ACE electronically transmits the entry data submitted by a filer at the time of entry to OASIS via an electronic interface. The entry is then initially screened by FDA using FDA’s Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting, a risk-based electronic screening tool for OASIS, to determine if automated or manual review of the entry is appropriate. An automated “*May Proceed*” determination is much faster and less resource intensive for FDA and the importer than a manual “*May Proceed*” determination. An automated “*May Proceed*” does not constitute a determination by FDA about the article’s compliance status, and it does not preclude FDA action at a later time. If the initial electronic review indicates that manual further review is appropriate, FDA personnel will review the entry information submitted by the ACE filer and may request additional information to make an admissibility determination and/or may examine or sample the FDA-regulated article.

ACE also allows importers to submit optional information relevant to FDA’s admissibility determination on veterinary devices. We strongly encourage the submission of the optional data elements in ACE at the time of entry if the importer of an FDA-regulated product is interested in an expedited admissibility review on its products (see the FDA Supplemental Guidance which includes the optional data elements published at:

<https://www.fda.gov/downloads/ForIndustry/ImportProgram/EntryProcess/ImportSystems/UCM533750.pdf>). Accurate and complete information submitted by a filer increases the likelihood that an entry line will receive an automated “May Proceed” determination from FDA.

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 Veterinary Devices*” which would (in pertinent part) extend the requirements of 21 CFR part 1 subpart D to veterinary devices (also referred to hereafter as “the proposed rule”) (85 FR 46566; August 3, 2020). The proposed rule would make the submission of the general data elements currently required to be submitted for other FDA-regulated products at the time of entry in ACE required for veterinary devices being imported or offered for import into the U.S.

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 number of FDA-regulated products imported into the United States has grown steadily, from approximately 6 million import entry lines in 2002 to over 35 million import entry lines in 2015. The proposed rule and this corresponding revision of this ICR would increase effective and efficient admissibility review by FDA of those entry lines containing a veterinary device, 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.

Import entry lines that include FDA-regulated products are electronically screened in FDA’s Operational and Administrative System for Import Support (OASIS) against criteria developed by FDA. FDA’s Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is a risk-based electronic screening tool for OASIS that performs this initial electronic screening by evaluating the entry information to determine potential risks associated with each entry line. OASIS expedites the clearance of FDA-regulated products that present a low public health risk, but only if the importer of record provides accurate, relevant, and complete entry information that will assist FDA in determining admissibility. If the FDA electronic review determines that further evaluation by FDA is warranted, FDA import entry review personnel will manually review the entry information and may request additional

information to make an admissibility determination and/or may examine or sample the FDA-regulated product.

The information collection aspects of the proposed rule would make the data elements that are required to be submitted for other FDA-regulated products in 21 CFR 1.72 also mandatory for the electronic filing of entries containing a veterinary device: FDA Country of Production; complete FDA Product Code; full intended use code; and telephone number and email address of the importer of record. Submission of these data elements in ACE would help us to more effectively and efficiently make admissibility determinations for veterinary devices by increasing the opportunity for automated “May Proceed” of these entries by FDA’s OASIS.

2. Purpose and Use of the Information Collection

This collection of information requires the submission in ACE of certain information, pursuant to the rule, for FDA-regulated products being imported or offered for import into the United States. The current rule requires entry filers to submit this information in ACE each time an entry is electronically submitted for an FDA-regulated product, except for veterinary devices. The proposed rule would make the data elements that are required to be submitted for other FDA-regulated products in 21 CFR 1.72 also mandatory for the electronic filing of entries containing a veterinary device. As noted above, this requested revision to the approved ICR will allow FDA to gather important and useful information about FDA-regulated products being imported or offered for import into the U.S., including data elements that were not collected in ACS. The collected information is used by FDA to initially screen and review FDA-regulated products being imported or offered for import into the U.S. for admissibility in order to prevent violative FDA-regulated products from entering the U.S. This action would facilitate automated “May Proceed” determinations by FDA for those veterinary devices that present a low risk to public health, which, in turn, would allow the agency to focus our limited resources on those FDA-regulated products that may be associated with a greater public health risk.

3. Use of Improved Information Technology and Burden Reduction

With the implementation of ACE, automated “May Proceed” determinations by FDA are expected to increase, and the international trade community will be able to more easily and efficiently import compliant FDA-regulated products into the U.S. 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 collection imposes no undue burden on small entities. As discussed in the Regulatory Impact Analysis (RIA) for the ACE final rule, FDA estimates that 40,452 out of the 41,703 importers are small businesses and that 3,630 out of the 3,667 entry filers are small businesses. As also discussed in the RIA, the ACE final rule will affect small businesses and larger businesses in a very similar manner and this will also be true for businesses that import veterinary device products. The total annual burden per respondent should generally scale linearly with the annual number of entry lines that include FDA-regulated products and that number should generally scale linearly in accordance with the size of the respondent's business. Furthermore, if needed, any filer can obtain assistance from their local FDA district, or from an FDA ACE help desk.

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 to add veterinary devices is vital for FDA to continue to prevent the importation of violative FDA-regulated products in a rapidly expanding, complex, and demanding international trade environment. If FDA were not able to collect FDA-specific data elements in ACE, 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 elements in the proposed rule are the key data/information that would most assist the agency

in making our initial admissibility determinations. By requiring certain data elements to be submitted in ACE at the time of filing entry, FDA expects that the number of import entries of FDA-regulated veterinary device products that may receive an automated “May Proceed” determination from FDA will increase. This will allow FDA to more effectively focus its limited resources on those FDA-regulated products being imported or offered for import that may be associated with a higher 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 published in the *Federal Register* of August 3, 2020 (85 FR 46566).

In developing the proposed rule and this associated collection of information, HHS/FDA has also consulted with appropriate agencies such as CBP and the Department of the Treasury.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

This information collection request (ICR) for the Proposed Rule is collecting personally identifiable information (PII) and other information of a personal nature. 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 telephone number and email address of the importer of record in the Automated Commercial System (ACE), operated by CBP, at time of entry of an animal device regulated by the FDA. 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/001 for 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

There are no questions asked of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Burden Estimate

Description of Respondents: Respondents to the information collection provisions of the proposed rule are those domestic and foreign importers of medical devices that import or offer to import veterinary devices into the United States and ACE filers.

Reporting: As of July 23, 2016, ACE became the sole EDI system authorized by CBP for the electronic filing of entries of FDA-regulated articles into the United States. FDA proposes to revise subpart D of part 1 of chapter I, which was recently added by the ACE final rule, to establish requirements for the electronic filing of entries of FDA-regulated products in ACE or any other EDI system authorized by CBP. That final rule took effect on December 29, 2016.

Currently, importers of certain FDA-regulated products must submit the general data elements in § 1.72 at the time of entry in ACE. We use the information collected to initially screen and review FDA-regulated products being imported or offered for import into the United States for admissibility in order to prevent violative FDA-regulated products from entering the United States. This proposed rule would make the data elements that are required to be submitted for FDA-regulated products pursuant to § 1.72 also mandatory for the electronic filing of entries containing a veterinary device: FDA Country of Production; complete FDA Product Code; full intended use code; and telephone number and email address of the importer of record. Submission of these data elements in ACE would help us to more effectively and efficiently make admissibility determinations for veterinary devices by increasing the opportunity for an automated “May Proceed” of these entries by FDA’s OASIS.

Although veterinary devices were not included in the ACE final rule, veterinary devices were included in its RIA, as aggregate data for both animal drugs and devices was included in the analysis. As a result of inadvertently including veterinary device import lines in the RIA of the ACE final rule, the information collection burden estimates of the ACE final rule likewise incorporated the importation of veterinary devices.

As stated above, the analysis of the collection of information and its related burden on respondents for the ACE final rule incorporated the one-time and recurring burden related to importation of veterinary devices by medical devices importers; thus, for this proposed rule there is no additional estimated burden beyond the burden hours that were included in the PRA section of the ACE final rule. We are, however, revising the information collection approved under OMB Control Number 0910-0046 to identify the subset of burden specific to the import entries for veterinary devices by importers of medical devices for the purpose of allowing stakeholders to comment on this subset.

The portion of the annual recurring reporting burden of this collection of information specific to importers of medical devices that import veterinary devices is estimated as follows:

Table 1.—Estimated Annual Recurring Reporting Burden ¹

Activity	Number of Respondents	Number of Responses per Respondent (approximate)	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Preparing the required information (applies to unique lines only)	654	0.60	392	0.03889 (2.333 minutes)	15
Quality checks and data submission into ACE	206	123.74	25,490	0.01944 (1.166 minutes)	496
Total Hours.....	511

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

We adopt the average burden per response estimates reported in table 1 from the analysis in the ACE final rule (81 FR 85854, at 85869). To estimate the number of respondents, number of responses per respondent, and total annual responses reported in table 1, we have used the relevant assumptions and estimates discussed in *Section VI. Economic Analysis of Impacts of the proposed rule*. Other key assumptions in the RIA for the ACE final rule and for this proposed rule that affect our estimate of the annual recurring reporting burden are:

- Average burden per response for preparing the required information that applies to *unique product-manufacturer import lines only* (81 FR 85854, at 85869). It is estimated to take between 0.0167 hours (1 minute) and 0.0667 (4 minutes), with the best estimate of 0.03889 hours (2.333 minutes).
- Average burden per response for quality checks and data submission into ACE applies to *all veterinary lines*. It is estimated to take between 0.0083 hours (0.5 minute) and 0.0333 hours (2 minutes) with the best estimate of 0.01944 hours (1.166 minutes).

Table 2.--Estimated One Time Reporting Burden¹

Activity	Number of Respondents	Number of Responses per Respondent (approximate)	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
First year adjusting to new requirements that will result in an average of 25 percent more time for quality checks and submission into ACE	206	119.74	24,667	0.00486 (0.29 minutes)	120

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

Table 2 shows the subset of the estimated one-time (i.e., occurring only in the first year) reporting burden associated specifically with the importation of veterinary medical devices by medical device importers. We adopt the average burden per response estimates reported in table 2 from the analysis in the ACE final rule (81 FR 85854, at 85869). We expect that, in the first year, respondents would be required to adjust to new requirements that will result in an average of 25 percent more time for quality checks and submission into ACE, for a total of 120 hours. Table 2 from the analysis in the ACE final rule (81 FR 85854, at 85869) also included an estimate of the time needed for review and familiarization with the rule. We have not included that estimate in this analysis because all importers of medical devices that import veterinary medical devices also import human medical devices, which are covered in the ACE final rule; thus, they are already familiar with those requirements.

If this rule is finalized as proposed, we estimate the subset of burden specific to the import entries for veterinary devices approved under OMB control number 0910-0046 to be 631 hours in the first year (511 recurring hours + 120 one-time hours) and 511 hours recurring after the first year.

12b. Annualized Cost Burden Estimate

As stated above, the analysis of the collection of information and its related burden on respondents for the ACE final rule incorporated the one-time and recurring burden related to importation of veterinary medical devices by medical devices importers. In accordance with the methodology used by the RIA for the ACE final rule, FDA is using a labor cost of \$74.91 (= (114.88 + 34.94) / 2), which is the average between the cost for a general and operations manager and the cost for an administration worker, and includes overhead costs and benefits. The total annualized cost burden estimate under this ICR would be \$125,205,472.92 in the first year (1,671,412 hours x \$74.91 per hour) and \$125,196,483.72 (1,671,292 hours x \$74.91 per hour) annually thereafter.

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. Because the costs of updating the existing software or purchasing new software is attributed to general use of the ACE system for making electronic import entries, FDA does not account for those costs in this ICR.

14. Annualized Cost to the Federal Government

Our current approval estimates an annual cost of an FDA import entry reviewer, in accordance with the methodology used by the RIA for the ACE final rule, to be \$250,000 accounting for overhead costs and benefits. The currently approved version of this ICR also estimates that 155 Full Time Equivalent (FTEs) are required to review the FDA-specific information on importers' entry notices. We do not expect the number of FTEs that are required to review importers' entry notices to change under the proposed rule, which would add veterinary devices. Accordingly, FDA is retaining its estimate of the annualized cost to the Federal government to \$38,750,000 per year ($=\$250,000 * 155$ FTEs).

15. Explanation for Program Changes or Adjustments

As stated above, the analysis of the collection of information and its related burden on respondents for the ACE final rule incorporated the one-time and recurring burden. This results in an additional 50,549 responses and 631 hours annually to the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No tabulation of the data is planned or anticipated.

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

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.