Airworthiness Limitations, Revision 16, dated September 2018, of the Dassault FALCON 900EX Maintenance Manual. The initial compliance times for accomplishing the actions are at the times specified in Chapter 5–40, Airworthiness Limitations, Revision 16, dated September 2018, or 90 days after the January 24, 2020, whichever occurs later, except as provided by paragraphs (g)(1) through (4) of this AD. Accomplishing the maintenance or inspection program revision required by paragraph (i) of this AD terminates the requirements of this paragraph.

(1) The term ''LDG'' in the ''First Inspection'' column of any table in the service information means total airplane landings.

(2) The term ''FH'' in the ''First Inspection'' column of any table in the service information means total flight hours.

(3) The term ''FC'' in the ''First Inspection'' column of any table in the service information means total flight cycles.

(4) The term ''M'' in the ''First Inspection'' column of any table in the service information means months since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness.

(h) Retained Restrictions on Alternative Actions and Intervals, With a New Exception

This paragraph restates the requirements of paragraph (j) of AD 2019–24–11, with a new exception. Except as required by paragraph (i) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (m)(1) of this AD.

(i) New Maintenance or Inspection Program Revision

Except as specified in paragraph (j) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2020–0116. Accomplishing the maintenance or inspection program revision required by this paragraph terminates the requirements of paragraph (g) of this AD.

(j) Exceptions to EASA AD 2020–0116

(1) The requirements specified in paragraphs (1) and (2) of EASA AD 2020–0116 do not apply to this AD.

(2) Paragraph (3) of EASA AD 2020–0116 specifies revising ''the approved AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, to incorporate the ''limitations, tasks and associated thresholds and intervals'' specified in paragraph (3) of EASA AD 2020–0116 within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2020–0116 is at the applicable ''associated thresholds'' specified in paragraph (3) of EASA AD 2020–0116, or within 90 days after the effective date of this AD, whichever occurs later.

(4) The provisions specified in paragraphs (4) and (5) of EASA AD 2020–0116 do not apply to this AD.

(5) The ''Remarks'' section of EASA AD 2020–0116 does not apply to this AD.

(k) New Provisions for Alternative Actions and Intervals

After the maintenance or inspection program has been revised as required by paragraph (i) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2020–0116.

(l) Terminating Actions for Certain Actions in AD 2010–26–05

Accomplishing the actions required by paragraph (g) or (i) of this AD terminates the requirements of paragraph (g)(1) of AD 2010–26–05, for Dassault Aviation Model FALCON 900EX airplanes, serial numbers 1 through 96 inclusive, and serial numbers 98 through 119 inclusive.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (n)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) For information about EASA AD 2020–0116, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0678.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3226; email *tom.rodriguez@faa.gov.*

Issued on July 27, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–16628 Filed 7–31–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2018–N–4268]

RIN 0910–AH66

Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), with the Department of the Treasury's concurrence, is proposing to amend its regulations to require that certain data elements be submitted for veterinary devices that are being imported or offered for import in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by U.S. Customs and Border Protection (CBP), in order for CBP to process the filing and to help FDA in determining the admissibility of that veterinary device. The proposed rule would make the submission of the general data elements currently required to be submitted in ACE for other FDA-regulated products at the time of entry also required in ACE for veterinary devices being imported or offered for import into the United States. This proposed rule 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.

DATES: Submit either electronic or written comments on the proposed rule

by October 19, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (PRA) by September 2, 2020.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 19, 2020; the *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 19, 2020; or comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–4268 for ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 office 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.

Submit comments on information collection issues under the PRA to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Importer's Entry Notice—OMB Control Number 0910–0046—Revision.''

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Randall Gnatt, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7231, *Randall.Gnatt@fda.hhs.gov. With regard to the information collection:* 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:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

For veterinary devices being imported or offered for import into the United States via ACE or any other EDI system authorized by the CBP, this proposed rule would require the submission of certain data elements material to FDA's process of making decisions on admissibility. 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.

B. Summary of the Major Provisions of the Proposed Rule

FDA proposes to revise subpart D of part 1 of 21 CFR chapter I (21 CFR part 1), which was added by a final rule issued by the Agency on November 29, 2016 (81 FR 85854), to establish requirements for the electronic filing of certain data elements for FDA-regulated products in ACE or any other EDI

system authorized by CBP. That final rule took effect on December 29, 2016.

This proposed rule would make the data elements that are required to be submitted for other FDA-regulated products in § 1.72 (21 CFR 1.72) also mandatory for the electronic filing of entries containing a veterinary device: (1) FDA Country of Production; (2) complete FDA Product Code; (3) full intended use code; (4) and telephone number and email address of the importer of record. Submission of these data elements in ACE would help FDA 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 Operational and Administrative System for Import Support (OASIS). These data elements are currently required to be submitted for the electronic filing of entries containing food contact substances, drugs, biological products, HCT/Ps, medical devices for human use, radiation-emitting electronic products, cosmetics, and tobacco products.

C. Legal Authority

The legal authority for this proposed rule includes sections 701 and 801 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371 and 381, respectively).

D. Costs and Benefits

Cost savings would result from increased efficiency in, and streamlining of, FDA's imports admissibility process. These cost savings to the industry and FDA cannot be quantified because FDA currently lacks data to do so. Potential benefits to consumers, that we are similarly unable to quantify, would result from a reduction in the number of non-compliant veterinary device imports reaching U.S. consumers and from compliant imported veterinary devices reaching U.S. consumers faster.

The FDA has estimated the annualized costs of complying with this proposed regulation to be between $0.028 million and $0.073 million per year (using 3 and 7 percent discount rates). These costs were already previously inadvertently included and the benefits were discussed in the regulatory impact analysis (RIA) for the ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment'' final rule (Ref. 2). We tentatively conclude that this proposed rule would have no additional costs beyond the costs that were included in that RIA (Ref. 2).

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
ACE	Automated Commercial Environment or any other CBP-authorized EDI system.
ACE filer	The person who is authorized to submit an electronic import entry for an FDA-regulated product in ACE.
ACS	Automated Commercial System—the predecessor CBP-authorized EDI system to ACE.
Agency	U.S. Food and Drug Administration.
CBP	U.S. Customs and Border Protection.
EDI	Electronic Data Interchange.
FDA	U.S. Food and Drug Administration.
FD&C Act	Federal Food, Drug and Cosmetic Act.
HCT/P	Human cells, tissues, or cellular or tissue-based products.
ITDS	International Trade Data System.
OASIS	FDA's Operational and Administrative System for Import Support.
RIA	Regulatory Impact Analysis.
PRA	Paperwork Reduction Act of 1995.
We, Our, Us	U.S. Food and Drug Administration.

III. Background

ACE is a commercial trade processing system operated by CBP that is designed to implement the International Trade Data System (ITDS), automate import and export processing, enhance border security, and foster U.S. economic security through lawful international trade and policy. FDA is a Partner Government Agency for purposes of submission of import data in ACE. As of July 23, 2016 (81 FR 32339), ACE became the sole EDI system authorized by CBP for entry of FDA-regulated articles into the United States.

On November 29, 2016 (81 FR 85854), FDA issued a final rule entitled ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment'' (the ACE final rule), which added subpart D to part 1 to require that certain data elements material to our import admissibility review be submitted in ACE at the time of entry. This proposed rule would add veterinary devices to the list of other FDA-regulated products being imported or offered for import for which the data elements required under § 1.72 must be submitted in ACE at the time of entry. The data elements in § 1.72 are FDA Country of Production, complete FDA Product Code, full intended use code, and telephone number and email address of the importer of record.

A veterinary device is a ''device'' as defined in section 201(h) of the FD&C Act (21 U.S.C. 321(h)) that is intended for use in animals. Section 201(h) of the FD&C Act defines ''device'' as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) Recognized in the official National Formulary, or the U.S. Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Manufacturers and distributors of veterinary devices are responsible for ensuring that these devices are safe, effective, and properly labeled. Under section 801(a) of the FD&C Act, FDA may refuse admission of veterinary devices being imported or offered for import that appear to be adulterated or misbranded. Devices, including veterinary devices, are subject to the adulteration provisions of section 501 of the FD&C Act (21 U.S.C. 351) and the misbranding provisions of section 502 of the FD&C Act (21 U.S.C. 352). We have determined that the data elements required to be submitted in ACE at the time of entry under § 1.72 are material to our import admissibility review of

veterinary devices. We expect that receipt of this information will increase the opportunity for automated ''May Proceed'' determinations by us for those veterinary devices that present a low public health risk 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.

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 by the Agency (see the FDA Supplemental Guidance which includes the optional data elements published at: *https://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM459926.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.

IV. Legal Authority

FDA has the legal authority under the FD&C Act to regulate the importation of veterinary devices into the United States (sections 701 and 801 of the FD&C Act). Section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act, while section 701(b) of the FD&C Act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the FD&C Act. This proposed rule is being jointly prescribed by FDA and the Department of the Treasury.

V. Description of the Proposed Rule

We are proposing to amend § 1.72 to make that section applicable to veterinary devices, as defined in proposed § 1.71. In addition, § 1.75 would be amended to include the requirement that the information in § 1.72 must be submitted in ACE at the time of entry for veterinary devices being imported or offered for import into the United States.

As explained in the Notice of Proposed Rulemaking entitled ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment'' published in the **Federal Register** of July 1, 2016 (81 FR 43155), CBP collected the data elements FDA Country of Production and the complete FDA Product Code to assist FDA in making admissibility decisions for FDA-regulated products. The FDA Country of Production data element identifies the country where an FDA-regulated article last underwent any manufacturing or processing but only if such manufacturing or processing was of more than a minor, negligible, or insignificant nature. The complete FDA Product Code data element is an alphanumeric code that we use for classification and analysis of regulated products. The FDA Product Code builder application allows ACE filers to locate or build the appropriate FDA Product Code. The complete FDA Product Code must be consistent with the invoice description submitted in ACE at the time of entry (§ 1.72(a)(2)). The FDA Product Code builder application is currently available on FDA's website at *https://www.accessdata.fda.gov/scripts/ora/pcb/.*

A full intended use code consists of a base code that designates the general use intended for the article and a subcode, if applicable, that designates the specific use intended for the article. Filers may submit the intended use code ''UNK,'' representing ''unknown,'' at the time of entry (81 FR 85854 at 85859–85860).

The email address and telephone number for the importer of record is also being required. This information will enable us to contact that person with any questions about the import entry as well as send notices of FDA actions, such as detention or refusal, electronically to that person (81 FR 43155 at 43161).

Section 1.75 codifies additional information that is required at the time of filing entry in ACE for animal drugs being imported or offered for import beyond that listed in § 1.72. The proposed rule would amend § 1.75 to include veterinary devices by: (1) Revising the section title to ''Animal drugs and veterinary devices''; (2) redesignating current § 1.75(a), (b), (c), and (d) to § 1.75(a)(1), (2), (3), and (4); and (3) adding § 1.75(b) Veterinary devices. Section 1.75(b) proposes that no additional information is required beyond that listed in § 1.72 for veterinary devices. Current § 1.75(d), redesignated to § 1.75(a)(4) by the proposed rule, if finalized, would be amended by adding the word ''file'' where the section refers to the ''investigational new animal drug number'' and by replacing the word ''application'' with ''file'' where the section refers to ''investigational new animal drug application.'' The section would thus use the more appropriate terminology ''investigational new animal drug file number'' and ''investigational new animal drug file,'' which would be consistent with the terminology used in other FDA regulations.

VI. Proposed Effective Date

We propose that any final rule based on this proposal become effective 30 days after the date on which it is published in the **Federal Register**.

VII. Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This

proposed rule would simply extend to veterinary devices the submission of the data elements that are currently required for other FDA-regulated imports covered under the ACE final rule (Ref. 1). The RIA for the ACE final rule estimates that: (1) Small businesses will be affected by that final rule in the same way as non-small businesses and that (2) small businesses would bear the costs, but would also enjoy most of the benefits (Ref. 2). According to FDA's internal data (Ref. 3), there are no businesses that solely specialize on importing veterinary devices into the United States. Because no additional businesses would be impacted by this proposed rule, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

For veterinary devices being imported or offered for import into the United States, and where entry is electronically filed in ACE or any other EDI system authorized by CBP, this proposed rule would require the submission of certain data elements material to FDA's process of making decisions on admissibility. This proposed rule therefore would simply extend to veterinary devices the submission of the data elements that are currently required for other products by § 1.72.

The costs of this proposed rule were inadvertently included and the benefits were discussed in the RIA for the ACE final rule (Ref. 2). More specifically, one data category that was used in the RIA of the ACE final rule included both animal drug import lines and veterinary device import lines and should have only included animal drug import lines. As a result of inadvertently including veterinary device import lines in the RIA of the ACE final rule, the costs of the ACE final rule were overestimated by $0.028 million to $0.073 million per year (using 3 and 7 percent discount rates) (table 1). These costs to industry [1] included the costs of preparing the required information for each import entry, checking data quality, and completing and submitting the electronic entry submission. We tentatively conclude that this proposed rule has no additional costs beyond the costs that were included in the RIA of the ACE final rule (Ref. 2).

Annualized over a 20-year horizon, the costs of complying with this proposed regulation are between $0.029 million and $0.073 million per year with the best estimate of $0.051 million per year at a 3 percent discount rate; these costs are between $0.028 million and $0.071 million per year with the best estimate of $0.049 million per year at a 7 percent discount rate (table 1).

TABLE 1—SUMMARY OF COSTS, BENEFITS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized, $millions/year	.....	.....	.....	.....	7	20	
					3	20	
Annualized Quantified	.....	.....	.....	.....	7	20	
					3	20	
Qualitative	Potential time reduction for veterinary device import entry processing by FDA; more efficient use of FDA's internal resources; potential increase in predictability of the import process for veterinary devices; potentially fewer veterinary device imports being held; potentially shorter timeframes for imported veterinary devices being held pending a final admissibility decision; potentially fewer recalls of imported veterinary devices; potential reduction in the number of violative veterinary devices entering the United States and reaching U.S. consumers; compliant imported veterinary devices potentially reaching U.S. consumers faster.						
Costs:							
Annualized Monetized, $millions/year	$0.049	$0.028	$0.071	2015	7	20	
	$0.051	$0.029	$0.073	2015	3	20	
Annualized Quantified	.....	.....	.....	.....	7	20	
					3	20	
Qualitative							
Transfers:							

[1] We assume that the importer would bear the actual burden of the ACE final rule even if the importer, for example, hires a customs broker to complete some of the tasks in order to comply with this regulation.

TABLE 1—SUMMARY OF COSTS, BENEFITS, AND DISTRIBUTIONAL EFFECTS OF THE PROPOSED RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Federal Annualized Monetized, $millions/year	.....	.....	.....	.....	7 3	20 20	
	From:			To:			
Other Annualized Monetized $millions/year	.....	.....	.....	.....	7 3	20 20	
	From:			To:			

Effects:

State, Local or Tribal Government: No significant effect

Small Business: Small businesses would be affected by this proposed rule, if finalized, in the same way as non-small businesses. Businesses that are affected by this rule are the same businesses as some of the importers affected by the ACE final rule because there are no businesses that solely specialize on importing veterinary devices into the United States. Small businesses that import veterinary devices would bear the costs of this rule, but also enjoy most of the benefits. We estimate that providing several additional data elements to FDA via ACE in exchange for a potentially more efficient import admissibility review process would not cause a significant impact on a substantial number of small entities. Benefits that we were not able to quantify arise from improved prevention of risks to public health from non-compliant veterinary device imports and increased efficiency and streamlining of the overall import process of veterinary devices; these benefits are presumed to be positive.

Wages: N/A.

Growth: N/A.

We are unable at this time to quantify exact resource savings to the Agency and cost savings to the industry because of the lack of data about certain industry practices and uncertainty about future changes in the usual and customary business practices, import volumes, and incoming data quality.

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. The present value of costs are approximately $0.77 million, discounted at 7 percent over an infinite time horizon, with a lower bound of approximately $0.45 million and an upper bound of approximately $1.12 million. The annualized costs of the proposed rule are approximately $0.054 million, discounted at 7 percent over an infinite time horizon, with a lower bound of approximately $0.031 million and an upper bound of approximately $0.078 million. Discounted at 3 percent over an infinite time horizon, the net present value of the costs of this proposed rule are approximately $2.03 million, with a lower bound of approximately $1.18 million and an upper bound of approximately $2.93 million. The annualized costs of the proposed rule are approximately $0.061 million, discounted at 3 percent over an infinite time horizon, with a lower bound of approximately $0.035 million and an upper bound of approximately $0.088 million. The proposed rule, if finalized as proposed, is expected to be an Executive Order 13771 regulatory action.

TABLE 2—SUMMARY OF EXECUTIVE ORDER 13771 COSTS

	Lower bound (7%)	Primary (7%)	Upper bound (7%)	Lower bound (3%)	Primary (3%)	Upper bound (3%)
Present Value of Costs	$449,016	$772,586	$1,117,741	$1,178,755	$2,027,690	$2,933,639
Present Value of Cost Savings	Not Quantified			Not Quantified		
Present Value of Net Cost Savings	Not Quantified			Not Quantified		
Annualized Costs	$31,438	$54,081	$78,248	$35,363	$60,831	$88,009
Annualized Cost Savings	Not Quantified			Not Quantified		
Annualized Net Cost Savings	Not Quantified			Not Quantified		

Next, we qualitatively discuss the cost savings, the benefits, and the costs of this proposed rule that were previously discussed in the RIA of the ACE final rule (Ref. 2) and would also apply to veterinary devices covered by this proposed rule. The cost savings to both the industry and FDA that we are unable to quantify would potentially arise from the reduced time of import entry processing for veterinary devices, fewer veterinary device imports being held, and a shorter timeframe between the time of veterinary device import entry transmission and a final

admissibility decision by FDA. Such time savings would arise as a result of increased efficiency in FDA's imports admissibility process.

Without this proposed rule, the amount of information provided by veterinary device import entry filers would be sub-optimal; the information material to FDA's determination of admissibility on an imported veterinary device would be collected only if and to the extent it is voluntarily provided by filers. In order to operate more efficiently and to make risk-based admissibility decisions potentially faster for all veterinary device import entries, FDA needs certain data elements. A manual review of a veterinary device entry line on average takes about 24 hours (Ref. 3), whereas an automated ''May Proceed'' outcome may take only minutes. Therefore, increasing the number of automated ''May Proceed'' outcomes results in time and cost savings to both FDA and industry. By requiring import entry filers to submit data elements mandated by this proposed rule into ACE, FDA intends to further streamline review of import entry declarations for veterinary devices and to facilitate a more efficient use of FDA's internal resources.

Potential benefits to consumers from this proposed rule that we are similarly unable to quantify would result from a reduction in the number of non-compliant veterinary device imports reaching U.S. consumers and from compliant imported veterinary devices reaching U.S. consumers faster. There have been recalls of imported veterinary devices in the past. For example, in 2016 there were three recalls of imported veterinary devices (Ref. 3). The potential health risk could be avoided if non-compliant veterinary devices are prevented from entering the U.S. market in the first place. FDA anticipates that requiring the data elements to be submitted in ACE for veterinary devices would reduce the number of violative veterinary devices entering the United States and consequently reaching American consumers. In some, but not in all cases, defects or adulteration of veterinary devices that are being imported or offered for import into the United States could be discovered upon a manual review that would be triggered as a result of information submitted in ACE.

In the RIA of the ACE final rule, we estimated that the costs to both domestic and foreign entities of complying with the rule as based largely on the amount of additional time it will take firms to: (1) Have an administrative worker prepare the additional information required for each import line; (2) have the owner or manager in charge confirm the information is correct; and (3) have an administrative worker complete the entry declarations using software that is connected to ACE. We also projected that the annual number of FDA-regulated import lines and the number of lines covered by the ACE final rule and therefore by this proposed rule would continue to grow at a rate of between 0 and 10 percent per year, with the most likely rate of 2.45 percent per year, resulting in increasing total annual costs to industry.

The estimated costs, cost savings, and benefits of the proposed rule are summarized in table 3. The lower and upper estimates are at the 5 and 95 percent confidence interval, respectively. The present discounted value of total costs over 20 years is $0.753 million at a 3 percent discount rate and $0.517 million at a 7 percent discount rate (table 3).

TABLE 3—SUMMARY OF ESTIMATED COSTS, COST SAVINGS, AND BENEFITS OF THE PROPOSED RULE

	Discount rate (%)	Lower estimate	Primary estimate	Upper estimate
Year 1 Costs		$27,007	$46,457	$67,213
Year 2 Costs		22,381	38,503	55,702
Year 3 Costs		23,120	39,774	57,540
Year 4 Costs		23,883	41,086	59,439
Year 5 Costs		24,671	42,441	61,400
Year 6 Costs		25,485	43,840	63,427
Year 7 Costs		26,326	45,290	65,520
Year 8 Costs		27,195	46,783	67,682
Year 9 Costs		28,092	48,324	69,915
Year 10 Costs		29,020	49,924	72,223
Year 11 Costs		29,977	51,571	74,606
Year 12 Costs		30,966	53,274	77,068
Year 13 Costs		31,988	55,026	79,611
Year 14 Costs		33,044	56,849	82,238
Year 15 Costs		34,134	58,724	84,952
Year 16 Costs		35,261	60,660	87,756
Year 17 Costs		36,424	62,654	90,652
Year 18 Costs		37,626	64,726	93,643
Year 19 Costs		38,868	66,871	96,733
Year 20 Costs		40,151	69,065	99,926
Total Costs		605,621	1,041,842	1,507,246
Present Discounted Value of Costs	3	437,739	753,036	1,089,427
Present Discounted Value of Costs	7	300,891	517,619	748,846
Annualized Costs	3	29,423	50,616	73,227
Annualized Costs	7	28,402	48,860	70,686
Total Benefits		Not Quantified		
Present Discounted Value of Benefits		Not Quantified		
Annualized Benefits		Not Quantified		
Total Cost Savings		Not Quantified		

TABLE 3—SUMMARY OF ESTIMATED COSTS, COST SAVINGS, AND BENEFITS OF THE PROPOSED RULE—Continued

	Discount rate (%)	Lower estimate	Primary estimate	Upper estimate
Present Discounted Value of Cost Savings		Not Quantified		
Annualized Cost Savings		Not Quantified		

Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. Because no additional business would be impacted by this proposed rule (Ref. 3), we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. Importers that are impacted by this proposed rule are the same businesses as some of the importers impacted by the ACE final rule (Ref. 1). The impacts on these small businesses are already discussed in the Regulatory Flexibility Analysis for the ACE final rule (Ref. 2).

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the one-time and recurring reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Importer's Entry Notice—OMB Control Number 0910–0046—Revision.

Description: This proposed rule would require that certain data elements material to our import admissibility review of veterinary devices be submitted in ACE or any other CBP-authorized EDI system, at the time of entry. This action would facilitate automated ''May Proceed'' determinations by us 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.

Description of Respondents: Respondents to the information collection provisions of this 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 4—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 4 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 4, we have used the relevant assumptions and estimates discussed in Section VI. Economic Analysis of Impacts. Other key assumptions in the RIA for the ACE final rule (Ref. 2) 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 5—ESTIMATED ONE TIME REPORTING BURDEN [1]

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 5 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 5 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.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title of the information collection. In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available

for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA. Submission of Food and Drug Administration Import Data in the Automated Commercial Environment. **Federal Register** (Docket No. FDA–2016–N–1487). Online November 29, 2016. Cited: January 31, 2017. *https://www.federalregister.gov/documents/2016/11/29/2016-28582/submission-of-food-and-drug-administration-import-data-in-the-automated-commercial-environment.*
2. FDA. Submission of Food and Drug Administration Import Data in the Automated Commercial Environment (Final Rule) Regulatory Impact Analysis. Economic Impact Analyses of FDA Regulations. Online November 29, 2016. Cited: January 31, 2017. *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/ucm530862.htm.*
3. FDA. Office of Regulatory Affairs Reporting, Analysis, and Decision Support System (ORADSS). 2015–2017 data.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350e, 350j, 350k, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 379j–31, 381, 382, 384a, 384b, 384d, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264, 271; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 111–353, 124 Stat. 3885, 3889.

■ 2. Amend § 1.71 by adding in alphabetical order the definition for ''Veterinary device'' to read as follows:

§ 1.71 Definitions.

* * * * *

Veterinary device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act, that is intended for use in animals.

* * * * *

■ 3. Revise § 1.72 introductory text to read as follows:

§ 1.72 Data elements that must be submitted in ACE for articles regulated by FDA.

General. When filing an entry in ACE, the ACE filer shall submit the following information for food contact substances, drugs, biological products, HCT/Ps, medical devices, veterinary devices, radiation-emitting electronic products, cosmetics, and tobacco products.

* * * * *

■ 4. Revise § 1.75 to read as follows:

§ 1.75 Animal drugs and veterinary devices.

(a) *Animal drugs.* In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE for animal drugs:

(1) *Registration and listing.* For a drug intended for animal use, the Drug Registration Number and the Drug Listing Number if the foreign establishment where the drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States is required to register and list the drug under part 207 of this chapter. For the purposes of this section, the Drug Registration Number that must be submitted in ACE at the time of entry is the Unique Facility Identifier of the foreign establishment where the animal drug was manufactured, prepared, propagated, compounded, or processed before being imported or offered for import into the United States. The Unique Facility Identifier is the identifier submitted by a registrant in accordance with the system specified under section 510(b) of the Federal Food, Drug, and Cosmetic Act. For the purposes of this section, the Drug Listing Number is the National Drug Code number of the animal drug article being imported or offered for import.

(2) *New animal drug application number.* For a drug intended for animal use that is the subject of an approved application under section 512 of the Federal Food, Drug, and Cosmetic Act, the number of the new animal drug application or abbreviated new animal drug application. For a drug intended for animal use that is the subject of a conditionally approved application under section 571 of the Federal Food, Drug, and Cosmetic Act, the application number for the conditionally approved new animal drug.

(3) *Veterinary minor species index file number.* For a drug intended for use in animals that is the subject of an Index listing under section 572 of the Federal Food, Drug, and Cosmetic Act, the Minor Species Index File number of the new animal drug on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.

(4) *Investigational new animal drug file number.* For a drug intended for animal use that is the subject of an investigational new animal drug or generic investigational new animal drug file under part 511 of this chapter, the number of the investigational new animal drug or generic investigational new animal drug file.

(b) *Veterinary devices.* An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE for veterinary devices.

Dated: July 2, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

In concurrence with FDA:

Dated: July 2, 2020.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy), Department of the Treasury.

[FR Doc. 2020–15571 Filed 7–31–20; 8:45 am]

BILLING CODE 4164–01–P

POSTAL SERVICE

39 CFR Part 113

New Mailing Standards for the Separation of Hazardous Materials

AGENCY: Postal Service™.

ACTION: Proposed revision; request for comment.

SUMMARY: The Postal Service proposes to amend Publication 52, *Hazardous, Restricted, and Perishable Mail* (Pub 52), to incorporate requirements for mailers to separate all air-eligible hazardous material (HAZMAT) from surface only transportation HAZMAT shipments and other non-HAZMAT items when tendering mail to the Postal Service in the domestic mail. Air eligible products, services or classes include Priority Mail Express®, Priority Mail®, First-Class Package Service®, Priority Mail Return Service® or First-Class Package Return Service® and surface only transportation are mail using Parcel Select®, Parcel Select Lightweight®, USPS Retail Ground®, or USPS Ground Return Service ®. Additionally, the Postal Service for consistency will incorporate the current standard operating procedures for separation as it pertains to acceptance and dispatch personnel.

DATES: We must receive your comments on or before September 2, 2020.