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[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: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), with the Department of the Treasury's concurrence, is amending 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 those veterinary devices. This final rule will 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 final rule will 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: This rule is effective November 17, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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I. Executive Summary

A. Purpose of the Final 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 rule requires the submission of certain data elements material to FDA's process of making decisions on admissibility. This action facilitates automated ''May Proceed'' determinations by FDA for those veterinary devices that present a low risk to public health which, in turn, allows 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 Final Rule

This rule revises 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), 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 rule makes 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 helps 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 import systems. These data elements are currently required to be submitted for the electronic filing of entries containing food contact substances, drugs, biological products, human cells, tissues or cellular or tissue-based products (HCT/Ps), medical devices for human use, radiation-emitting electronic products, cosmetics, and tobacco products.

C. Legal Authority

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

D. Costs and Benefits

Cost savings 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, will 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 annualized costs of complying with this regulation are estimated to be between $0.056 million and $0.140 million per year (in 2020 dollars annualized over 20 years using 7 percent discount rate). These costs were already previously inadvertently included and the benefits discussed in the regulatory impact analysis (RIA) for the ''Submission of Food and Drug Administration Import Data in the Automated Commercial Environment'' 2016 final rule. Because we do not want to double count these costs to the industry, we have concluded that this final rule will have no additional costs beyond the costs that were included in that RIA.

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.
RIA	Regulatory Impact Analysis.
PRA	Paperwork Reduction Act of 1995.
We, Our, Us	U.S. Food and Drug Administration.

III. Background

A. Need for the Regulation/History of This Rulemaking

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, 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 rule adds 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. Further, such device does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and 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 (21 U.S.C. 381(a)), 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. Receipt of this information increases the opportunity for automated ''May Proceed'' determinations by us for those veterinary devices that present a low public health risk which, in turn, allows 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 FDA via an electronic interface. The entry is then initially screened by FDA using FDA's Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), a risk-based electronic screening tool, 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 later. If the initial electronic review indicates that manual review is appropriate, FDA personnel will review the entry information submitted by the entry 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 Guide which includes the optional data elements published at: *https://www.cbp.gov/sites/default/files/assets/documents/2021-Sep/FDASupplementalGuideVersion2.5.5_508c%28003%29%281%29.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.

B. Summary of Comments to the Proposed Rule

We received four comments on the proposed rule by the close of the comment period, all from individuals. One comment is unintelligible. The remaining three comments from individuals made general remarks supportive of the proposed rule. All suggested extending the beneficial aspects of the proposed electronic submission of the general data elements for veterinary devices to other FDA-regulated products. A requirement for this specific process in the ACE environment for other FDA-regulated products was established under the ACE final rule, which was effective in December 2016. We are finalizing the proposed rule without revision.

C. General Overview of the Final Rule

FDA is amending § 1.72 to make that section applicable to veterinary devices, as defined in proposed § 1.71. In addition, we are amending § 1.75 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, prior to ACE, in the Automated Commercial System (ACS), operated by CBP for the submission of electronic entries, 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. entry filers need to be aware that submitting ''UNK'' as the intended use code will, in most cases, subject the entry to a manual review for admissibility provided the entry filing is not rejected by FDA (81 FR 85854 at 85859 to 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 an entry in ACE for animal drugs being imported or offered for import beyond that listed in § 1.72. The final rule amends § 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) states 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 final rule, is being 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.'' This is a technical amendment for the purpose of using the more appropriate terminology ''investigational new animal drug file number'' and ''investigational new animal drug file'' in that section, which is consistent with the terminology used in other FDA regulations.

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 final rule is being jointly prescribed by FDA and the Department of the Treasury.

V. Comments on the Proposed Rule and FDA Response

We received four comments on the proposed rule by the close of the comment period, all from individuals. One comment is unintelligible. The remaining three comments make brief general remarks supportive of the proposed rule; all suggest extending the beneficial aspects of the proposed electronic submission of general data elements for veterinary devices to other FDA-regulated products. A requirement for this specific process in the ACE environment for such other FDA-regulated products was created under the ACE final rule in 2016. Because these comments were outside the scope of this rule, further discussion of them is not included here.

We are finalizing the proposal without revision.

VI. Effective Date

The rule is effective November 17, 2022.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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). We believe that this final 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 final rule simply extends 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 will bear the costs, but will 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 will be impacted by this final rule, we certify that this final 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 issuing ''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 $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final 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 final rule requires the submission of certain data elements material to FDA's process of making decisions on admissibility. This final rule therefore simply extends to veterinary devices the submission of the data elements that are currently required for other FDA-regulated products by § 1.72.

The costs of this final rule were inadvertently included, and the benefits 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 $0.071 million per year (in 2015 dollars, annualized over 20 years using a 7 percent discount rate). 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. Because we do not want to double count these costs to the industry, we conclude that this final rule has no additional costs beyond the costs that were included in the RIA of the ACE final rule (Ref. 2). Updated to 2020 dollars and using actual import line counts for years since the publication of the ACE final rule (2016 to 2020), the costs of complying with this regulation are between $0.056 million and $0.140 million per year with the best estimate of $0.077 million per year at a 7 percent discount rate and are between $0.059 million and $0.147 million per year with the best estimate of $0.080 million per year at a 3 percent discount rate (table 1).

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

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized, $millions/year							
Annualized Quantified							
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	$0.077	$0.056	$0.140	2020	7	20	
Annualized Quantified	0.080	0.059	0.147	2020	3	20	
Qualitative							
Transfers:							
Federal Annualized Monetized, $millions/year							
	From:			To:			

[1] We assume that the importer bears 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 FINAL RULE—Continued

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

Effects:

State, Local or Tribal Government: No significant effect.

Small Business: Small businesses are affected by this final rule 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 will bear the costs of this rule, but also will 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 will 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.

Next, we qualitatively discuss the benefits and the costs of this final rule that were previously discussed in the RIA of the ACE final rule (Ref. 2) and will also apply to veterinary devices covered by this final rule. The cost savings to both the industry and FDA that we are unable to quantify 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 will arise as a result of increased efficiency in FDA's imports admissibility process.

Without this final rule, the amount of information provided by veterinary device import entry filers would be suboptimal; 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 final rule into ACE, FDA will further streamline review of import entry declarations for veterinary devices and will facilitate a more efficient use of FDA's internal resources.

Benefits to consumers from this final rule that we are similarly unable to quantify will 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 will 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 will be discovered upon a manual review that will be triggered as a result of information submitted in ACE.

In the RIA of the ACE final rule, we estimate 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 final 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. For years since the publication of the ACE final rule (2016 to 2020), we replaced this assumption with actual veterinary device import line counts.

The estimated costs of this final rule are summarized in table 2. The lower and upper estimates are at the 5 and 95 percent confidence interval, respectively. Updated to 2020 dollars, the present value of total costs of this rule is $0.81 million at a 7 percent discount rate and $1.19 million at a 3 percent discount rate.

TABLE 2—SUMMARY OF ESTIMATED COSTS, COST SAVINGS, AND BENEFITS OF THE FINAL RULE

[In thousands of 2020 dollars]

	Discount rate (%)	Lower estimate	Primary estimate	Upper estimate
Year 1 Costs		$29	$49	$73
Year 2 Costs		39	53	97
Year 3 Costs		51	69	127
Year 4 Costs		52	71	130
Year 5 Costs		51	69	127
Year 6 Costs		53	71	131

TABLE 2—SUMMARY OF ESTIMATED COSTS, COST SAVINGS, AND BENEFITS OF THE FINAL RULE—Continued

[In thousands of 2020 dollars]

	Discount rate (%)	Lower estimate	Primary estimate	Upper estimate
Year 7 Costs		54	74	136
Year 8 Costs		56	76	140
Year 9 Costs		58	78	145
Year 10 Costs		60	81	149
Year 11 Costs		62	84	154
Year 12 Costs		64	86	159
Year 13 Costs		66	89	165
Year 14 Costs		68	92	170
Year 15 Costs		71	95	176
Year 16 Costs		73	98	182
Year 17 Costs		75	102	188
Year 18 Costs		78	105	194
Year 19 Costs		80	109	200
Year 20 Costs		83	112	207
Total Costs		1,225	1,663	3,048
Present Value of Costs	7	596	813	1,483
Present Value of Costs	3	878	1,194	2,185
Annualized Costs	7	56	77	140
Annualized Costs	3	59	80	147
Total Benefits		Not Quantified		
Present Value of Benefits		Not Quantified		
Annualized Benefits		Not Quantified		

Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Veterinary device importers that are impacted by this final rule are included in the Final Regulatory Flexibility Analysis for the ACE final rule (Ref. 2). As such, the impacts on these small businesses are already discussed in the Regulatory Flexibility Analysis for the ACE final rule (Ref. 2). This analysis serves as the Final Regulatory Flexibility Analysis for this rule, as required under the Regulatory Flexibility Act. Because no additional business will be impacted by this final rule (Ref. 3), we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

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 final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (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.

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

Description: We are issuing a regulation that requires ACE filers to submit certain data elements material to our import admissibility review of veterinary devices in ACE, or any other CBP-authorized EDI system, at the time of entry. This action facilitates automated ''May Proceed'' determinations by us for those veterinary devices that present a low risk to public health which, in turn, allows 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 final 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 has revised 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 final rule makes 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.

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 final 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 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent (approximate)	Total annual responses	Average burden per response	Total hours
Preparing the required information (applies to unique lines only)	944	0.51	484	0.03889 (2.333 minutes)	19
Quality checks and data submission into ACE	285	117.87	33,592	0.01944 (1.166 minutes)	653
Total	.....	.....	.....	.....	672

[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 3 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 3, we have used the relevant assumptions and estimates discussed in Section VI. Economic Analysis of Impacts and the actual data for 2016 to 2018. Other key assumptions in the RIA for the ACE final rule (Ref. 2) and for this final 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 device 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 4—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent (approximate)	Total annual responses	Average burden per response	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 4 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 4 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.

We estimate the subset of burden specific to the import entries for veterinary devices approved under OMB control number 0910–0046 to be 792 hours in the first year (672 recurring hours + 120 one-time hours) and 672 hours recurring after the first year.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this final 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 final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the final 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 this final 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 final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the final rule does not contain policies that have substantial direct effects 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

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. *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. *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*
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, 21 CFR part 1 is 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, 384, 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: October 6, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

In concurrence with FDA.

Dated: October 6, 2022.

Thomas C. West, Jr.,

Deputy Assistant Secretary of the Treasury for Tax Policy, Department of the Treasury.

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DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 518

RIN 3141–AA72

Self-Regulation of Class II Gaming

AGENCY: National Indian Gaming Commission, Department of the Interior.