U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Submission of FDA Import Data in the Automated Commercial Environment

Regulatory Impact Analysis for Final Rule

Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

FDA-2016- N-1487

Economics Staff
Office of Planning
Office of Policy, Planning, Legislation and Analysis
Office of the Commissioner
November 2016

SUMMARY: Pursuant to Executive Order 13569, the U.S. Customs and Border Protection (CBP) agency established a new commercial trade processing system called the Automated Commercial Environment (ACE). ACE has replaced the Automated Commercial System (ACS), which was the processing system formerly used by CBP for import admissibility decisions. The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to establish requirements for the electronic filing of entries of certain FDA-regulated products in the ACE or any other electronic data interchange system authorized by the CBP, in order for the import entry filing to be processed by CBP and to help FDA in determining admissibility. This final rule concerns only the data elements for which the submission will be made mandatory in ACE. These elements would be collected for FDA by CBP via ACE to facilitate FDA's process of making admissibility decision on certain FDA-regulated commodities imported or offered for import into the United States. Requiring submission of these data elements in ACE will help the Agency to prevent some products that are not in compliance with the FD&C Act or the Public Health Service (PHS) Act, or that are otherwise subject to refusal of admission, from entering the U.S. and to improve efficiency of the FDA import entry process. In addition, this rule also establishes technical revisions to certain sections of 21 Code of Federal Regulations (CFR) Chapter I related to (1) updating the definition of owner or consignee; (2) updating the procedure for providing notice of sampling; (3) clarifying that FDA can provide electronic notices of hearing on refusal of admission or destruction related to FDA-regulated products imported or offered for import; and (4) specifying that importers of record of human cells, tissues or cellular or tissue-based products (HCT/Ps) that are regulated solely under section 361 of the PHS and 21 CFR part 1271, unless exempted, would be required to submit the applicable data elements included in this final rule in ACE. The analysis of benefits and costs included in this document is the basis for the summary analysis included in the Economic Analysis of Impacts section of the Electronic Submission of Import Data: Automated Commercial Environment final rule [FDA-2016- N-1487].

Table of Contents

Summary of Economic Analysis of Impacts of the Final Rule

As of July 23, 2016, ACE became the sole electronic data interchange system authorized by CBP for entry processing of FDA-regulated imports into the United States. FDA is finalizing a rule to establish requirements for the electronic filing of import entries. The final rule will require that certain data elements material to FDA's process of making import admissibility decisions into the U.S. be submitted to the FDA via ACE as a part of an electronic import entry declaration. This regulation will help streamline FDA's existing admissibility procedures for FDA-regulated commodities imported or offered for import into the United States. For import entry declarations submitted electronically, FDA will require that certain key data be submitted as part of the import entry declaration filing in ACE. The regulation also provides further clarifications to the import process by revising sections of 21 CFR Chapter I relating to the definition of owner or consignee; the notice of sampling; and the notices of FDA actions to sample, refuse, and/or subject to administrative destruction certain FDA-regulated products imported or offered for import into the U.S. and allowing for electronic notification by FDA. Additionally the regulation specifies that importers of record of human cells, tissues or cellular or tissue-based products (HCT/Ps) that are regulated solely under section 361 of the PHS Act and 21 CFR part 1271, unless exempted, will be required to submit the applicable data elements included in the final rule in ACE.

This regulatory impact analysis (RIA) analyzes the economic impacts of the final rule, including estimates of costs, benefits, and cost savings. It quantifies the costs of the final rule to the society by estimating the costs associated with submitting the new data elements in ACE. This RIA also analyzes and qualitatively discusses benefits of this final rule.

Costs of complying with this final rule would be incurred by firms that import or offer for import into the U.S. products that are subject to FDA regulation and covered by the final rule. The main impact of this final rule on these firms would be that as a part of import entry declaration, ACE entry filers would have to submit into ACE new mandatory information. The type of information and hence the costs and benefits would vary depending on the product type, the existing business practices, and on whether filers were already submitting some of this information into ACS for FDA based on information provided by the importer.[1] The estimated costs of this final rule – and the cost savings compared to the baseline scenario – stem from the mandatory information that will be submitted and collected under the ACE system. In the baseline scenario for our estimates of these costs, we assumed that without this final FDA regulation the information would be collected by ACE only if and to the extent it is voluntarily provided by filers, like under the former ACS system (Table 1).

Table 1. Total Annualized Costs and Benefits of the Final Rule [2]

Discount Rate	Total Annualized Costs	Total Benefits	
		Cost Savings	Other Benefits (Not Quantified)
3 percent	$46.7 million (range $27.7 million to $69.1 million)	$21.0 million (range $2.6 million to $43.4 million)	Potential time reduction for processing import entry declarations by FDA; potential increase in predictability of the import process; potentially shorter timeframes for imported products being held pending a final admissibility decision ; more efficient use of FDA's internal resources; potentially fewer recalls of imported products; reduction of counterfeit and misbranded imports on the U.S. market; increased efficiency of the overall import process due to decreased ambiguity because of a better defined *the owner or consignee*

[1] In this RIA, we do not include benefits and costs from data elements that were being routinely submitted by some filers into ACS.

[2] We generated upper and lower bounds using Monte Carlo simulations.

			term, the clarifications related to notice of sampling, and allowing for electronic notice of certain FDA actions related to hearing on refusal of admission of imports and destruction of drugs.
7 percent	$45.1 million (range $26.8 million to $66.7 million)	$21.0 million (range $2.6 million to $43.4 million)	Potential time reduction for processing import entry declarations by FDA; potential increase in predictability of the import process; potentially shorter timeframes for imported products being held pending a final admissibility decision ; more efficient use of FDA's internal resources; potentially fewer recalls of imported products; reduction of counterfeit and misbranded imports on the U.S. market; increased efficiency of the overall import process due to decreased ambiguity because of a better defined *the owner or consignee* term, the clarifications related to notice of sampling, and allowing for electronic notice of certain FDA actions related to hearing on refusal of admission of imports and destruction of drugs.

We estimate that in the first year the costs of this final regulation will range from $25.5 million to $63.7 million, with the best estimate of $43.0 million.[3] In the steady state, the best estimate costs will range from $35.5 million to $63.7 million per year. Table 1 shows the total costs, cost savings, and other benefits of this final rule; the costs and cost savings are reported on an annualized basis using a 3 and a 7 percent discount rate over a 20 year time horizon. Annualized over a 20 year horizon, the costs of complying with this regulation are between $27.7 million and $69.1 million per year with the best estimate of $46.7 million per year with a 3 percent discount rate; these costs are between $26.8 million and $66.7 million per year with the best estimate of $45.1 million per year with a 7 percent discount rate (Table 1). The present discounted value of total costs of the final rule is $694.4 million at a 3 percent discount rate and $477.3 million at a 7 percent discount rate. The per-importer annualized cost is $1,119 with a 3 percent discount rate and $1,080 with a 7 percent discount rate.

[3] We generated upper and lower bounds using Monte Carlo simulations.

The total annualized cost savings to society cannot be fully quantified because of the lack of certain data currently available to the Agency. Partially quantifiable cost savings are estimated to range from $2.6 million to $43.4 million, with the best estimate of $21.0 million per year with a 3 percent discount rate; these partially quantifiable benefits are estimated to range from $2.6 million to $43.4 million, with the best estimate of $21.0 million per year with a 7 percent discount rate (Table 1). The per-importer annualized benefits that we were able to quantify are $355 with a 3 percent discount rate and $355 with a 7 percent discount rate. Benefits, in terms of cost savings, to both FDA and the industry that we are able to quantify would arise from FDA simplifying the notification process on certain FDA actions taken by the Agency under section 801 of the FD&C Act by allowing electronic notification of the owner or consignee.

Some of the cost savings to both the industry and FDA that we are unable to quantify will potentially arise from the reduced time of import entry declarations processing, fewer imported products being held and a shorter timeframe between the time of entry transmission and a final admissibility decision by FDA as a result of increased efficiency in FDA's imports admissibility process. Other potential benefits of this final rule that we are unable to quantify would result from compliant FDA-regulated imports reaching U.S. consumers faster and a reduction in the number of non-compliant imports reaching U.S. consumers, thereby making the overall supply of FDA-regulated products on the U.S. market safer. Other potential benefits in the form of cost savings that we are similarly unable to quantify would also arise because by revising certain sections of 21 CFR Chapter I the Agency would provide more clarity to the industry about certain aspects of the overall process of importing FDA-regulated products. These aspects include (1) updating the definition of owner or consignee; (2) updating the procedure for

providing notice of sampling; and (3) clarifying that FDA can provide electronic notices of hearing on refusal of admission or destruction related to FDA-regulated products imported or offered for import.

I. INTRODUCTION

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 (Public Law 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 have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a 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. By requiring import entry filers to submit data elements mandated by this final rule into ACE and updating certain sections of 21 CFR Chapter I, we intend to streamline import entry declarations and reduce ambiguity about the import process. Small businesses will be affected by this final rule in the same way as non-small businesses. Because the burden of switching from ACS to ACE is already covered by CBP's ACE regulation, for those small business filers that choose to continue filing electronically (and, therefore, must use ACE), we believe that providing several additional data elements to FDA via ACE in exchange for a more streamlined process and potentially receiving an import

admissibility decision faster would not cause a significant impact. These small businesses would bear the costs of this final rule, but would also enjoy most of the benefits. We therefore certify that the 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 $146 million, using the most current (2015) 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.

A. Need for This Regulation

This final rule seeks to improve FDA's ability to protect public health by specifying certain required data elements be submitted as part of an import entry declaration filing via ACE. This regulation also provides clarification to the import process by revising certain sections of the 21 CFR Chapter I language related to the import process and to electronic notification about hearings on refusal of admission or administrative destruction.

Globalization of world markets has increased importation of FDA-regulated products into the U.S. In the drug and medical device markets, for example, development of complex and fragmented global supply chains transformed these industries and resulted in increased import of ingredient components and finished products. With this increase in globalized trade has also come the increased threat that counterfeit and substandard FDA-regulated products will be

offered for import into the U.S. This example illustrates one of many new challenges FDA faces in protecting public health with respect to importation of FDA-regulated products. Even though importers and other businesses that may be impacted by this final rule have powerful private incentives to avoid having contamination linked to their imported cargo or production facilities, those private incentives are not enough for firms to provide the optimal amount of information to FDA about their imports and collectively provide the information about the global distribution system process as a whole as may relate to public health and safety.

Global distribution systems are becoming more complex and, although private incentives lead to private efforts to protect product safety and quality at the firm level because the consequences could be costly for that firm, there are external effects associated with privately produced information and protection. Private incentives are insufficient to provide the optimal amount of information about the entire import production and distribution system. The system works using local knowledge and information, and each participant of the import supply chain needs to know only as much about the overall import process as is necessary for his or her business. Although market prices and incentives typically convey most of the information necessary for the ordinary production, distribution, and delivery of imported goods, more complete information is needed where it can be centrally used. This goal of more complete information will not be realized if private incentives alone guide collection and provision of such information on FDA regulated imports.

No individual firm or organization has sufficient financial incentives to establish a central information system (such as ACE) for trade processing that tracks, controls, and processes all import entries of commercial goods into the United States. All participants in the import industry, however, benefit from such a system because it facilitates problem solving associated

with products being imported or offered for import into the U.S. The private costs to create such a system probably would be prohibitive for any single firm or third party organization. We estimate that an effective system of information would require several thousand participants to gather information and provide it to a central system. The private transaction cost to bring all the participants together voluntarily and get them to agree to create such a system would be extraordinarily high. No single organization could capture additional revenue sufficient to cover such a cost.

Under the former ACS system, which was a centralized non-private information system, the amount of information provided by filers into ACS for FDA was sub-optimal. Although ACS did provide FDA with some important voluntary import entry information, filers who spent additional time and resources to provide more information to FDA (via ACS) than was required for an import entry decision may have resulted in faster 'may proceed' decisions by FDA, but for fewer import entry declarations than potentially can happen under ACE. This is in part because of the way ACS was designed and operated and in part because to make risk-based evaluations and admissibility decisions potentially faster, FDA needs additional new data elements beyond what was required in ACS. As a result of firms not providing the necessary information to FDA, FDA was unable to operate as efficiently as possible when making risk-based import entry decisions as it will be able to with newly-required data elements submitted through ACE.

More generally, the need for improving the efficiency of the overall import process is emphasized by Executive Order 13569. ACE is the electronic import system that importers of record must now use for electronically filing import entry declarations; ACE is designed to simplify and streamline the import process. This year (2016), ACE replaced the ACS that was operated by CBP for import processing. Key to ACE is the new way of submitting trade

information called International Trade Data System (ITDS). The ITDS was established to modernize and simplify the way in which Partner Government Agencies (PGAs), including FDA, interact with importers by creating a "single-window" capability of ACE that allows businesses to submit all data required by PGAs for import and export cargo processing into a single portal.[4] ACE electronically transmits this trade information to the multiple agencies with jurisdiction over the particular products being imported, including FDA.

B. Coverage of the Analysis

In order to assess the total costs and cost savings of this final rule, we estimate the costs for each provision and apply these values to either the number of affected U.S. and foreign entities or to the number of affected import lines.

Table 2. The total number of U.S. and foreign entities that are involved in import of FDA-regulated commodities impacted by this final rule, 2015

Entity type	US entity	Foreign entity	Total
Importers (owners and purchasers)	34,502	7,201	41,703
Filers	3,667	0	3,667
Ultimate Consignees	380,277	0	380,277
Foreign manufacturers	0	183,837	183,837
Shippers	181,170		181,170

The regulated community for this final rule consists of firms that offer FDA-regulated products for import into the U.S. and would file electronic entry declarations with CBP via ACE. Based on the FDA internal 2015 data [1], we estimate there are about 41,703 importers of FDA-

[4] This final rule-making would only concern import cargo.

regulated commodities that would be potentially impacted by this final rule (Table 2); about 83 percent of them are U.S. firms. These importers either file these electronic import entry declarations and the required data in ACE themselves or hire a customs broker licensed by CBP.[5] Although other types of entities may be involved in the entire process of import entry from data collection to transmission of the entry data into ACE, we assume that the importer would bear the actual burden of this final rule even if the importer, for example, hires a customs broker to complete some of the tasks in order to comply with this final regulation. We estimate that there are a total of 3,667 entry filers, which includes the 959 owners or purchasers of the article who will file their own import entry in ACE (= 41,703 owners or purchasers of the article offered for import x (100-97.7) percent).

In the absence of data about the size or annual sales of import entry filers, we follow Small Business Administration's (SBA) small business definition for 'Wholesale agents and brokers' NAICS code 425120 [2] and SBA's data [3] and estimate that approximately 99 percent of all wholesale trade agents and brokers employ fewer than 100 employees and therefore are small businesses. In the absence of data about the size or annual sales of importers, we borrow from the economic analysis of the Food Safety Modernization Act Foreign Supplier Verification Program (FSMA FSVP) rule in assuming that importers are equivalent in their characteristics to importers described in the FSMA FSVP rule and that approximately 97 percent of importers are small businesses [4].[6] Based on these assumptions, we estimate that 40,452 out of 41,703 importers that would be affected by this final rule are small businesses and that 3,630 out of

[5] A filer is an entity that files an import entry declaration with CBP; a filer can be a customs broker licensed by CBP or an importer itself. Based on the FDA internal information, we estimate that between 92 and 99 percent with a best estimate of 97.7 percent of importers use brokers to file import entries [1].

[6] In the economic analysis of the FSMA FSVP rule, it is estimated that 97 percent of importers are businesses with fewer than 500 employees [4, p. 115]. We assume that it is likely that importers that import foods covered by the FSMA FSVP rule also import imports covered by this regulation. We also assume that that size distribution among these businesses is similar to the ones covered by the FSMA FSVP rule.

3,667 entry filers are small businesses. In the PRIA we requested comments on our estimates of the number of importers, customs brokers, and other entry filers that are small businesses and would be covered under this final rulemaking; we received no comments on our estimates.

According to CBP, currently 96 percent of import entry declarations are filed electronically[7] [5]. We estimate that in 2015, FDA processed a total of 35.4 million import lines of FDA-regulated products [1]. We then estimate that about 23.1 million[8] import lines would be covered by the final rule because they were submitted electronically and are for products covered by this rulemaking. According to FDA internal data [1], in 2015 about 2.2 percent of all import lines represented unique product-manufacturer combinations.

II. COSTS AND BENEFITS OF REGULATORY OPTIONS

For purposes of this analysis, we assume that it would take the same amount of time for domestic and foreign filers to comply with the final rule if foreign importers are fluent in English and thus do not need more time to complete certain tasks. If importers themselves are not fluent in English, their customs brokers are able to explain to their foreign language speaking clients (importers) what information is needed. Therefore, we assume that even if the importing businesses themselves are not fluent in English, their customs brokers handle this aspect of the business for them as a usual and customary practice.

[7] Importers can file entry declarations and the supporting documentation with CBP and FDA either electronically or by paper for both PGAs. It is up to CBP to decide whether to continue accepting non-electronic entries in the future. Please note that entities that choose to file entry declarations by paper would not be impacted by the final rule but remain subject to CBP requirements in ACE.

[8] Each import entry may contain multiple lines. According to the FDA internal data, about 8.4 million import entries with 35.4 million import lines were processed by FDA in 2015, including 24.1 million lines of products that would be covered by this final rulemaking [9]. We estimate that about 23.1 million electronically-filed import lines (= 24.1 million lines x 0.96) will be affected by this final rule.

For the purposes of this analysis, all activities are considered in the context of a typical scenario in which importers may employ brokers who act on their behalf in filing the information into ACE/ITDS as a part of an import entry declaration. Under such a scenario, even though brokers act as actual filers of information, the understanding is that the information originates from importers[9] that would carry the actual burden and is simply provided by importers to brokers.[10] This allows estimating the total cost of the final rule by multiplying per importer cost by the total number of importers and per import line cost by the total number of covered import lines.

A. Baseline

Establishing ACE, the interface system that supports the "single window" capability of the ITDS, is mandated by President Obama's Executive Order 13569. Accordingly, not switching from ACS to ACE was not a viable option and cannot be the baseline for this analysis. Under the baseline of no regulation, FDA would continue receiving some voluntary data from the industry, but would still have to finish linking CBP's ACE to FDA's internal decision-making system because CBP will decommission ACS. As such, there would be no additional benefits but there would be costs to FDA to change to the new system under the baseline.

Currently, filers that choose to file import entry declarations electronically interact with CBP through the Automated Broker Interface (ABI).[11] The data filed by these filers then gets

[9] Many of these importers are firms that are required by law or regulation to have some of this information in their records.

[10] An importer of record is the owner or purchaser of the article being offered for import or a customs broker licensed by CBP under 19 U.S.C. 1448(b) who has been designated by the owner, purchaser, or consignee to file the import entry. Under this scenario, an importer hires a broker because it is more cost effective for an importer to pay broker's fee and acquire all costs of day-to-day dealings with a broker than to handle ACE entry submissions on their own.

[11] CBP reports that current entry submission methods include electronic and non-electronic (paper) formats, although most import entry declarations are submitted electronically [5]. Submitters that choose to file manually

automatically transmitted from ABI into CBP's ACE system for processing. The ACE interface is directly linked to FDA's Operational and Administrative System for Import Support (OASIS) that facilitates admissibility decisions of FDA-regulated imports into the U.S.

CBP collected, via ACS, four data elements that assist FDA in making admissibility decisions for FDA-regulated articles:

(1) The complete FDA Product Code,

(2) FDA country of production,

(3) FDA manufacturer and shipper,

(4) The ultimate consignee.

In addition, CBP collected on behalf of FDA certain "affirmations of compliance," which vary by type of product. Providing this information voluntarily in ACS often helped expedite making an import admissibility decision by FDA, resulting in time savings to the importer, their trading partners, and FDA.[12,13]

Table 3. The Number of Import Lines and Baseline Compliance for FDA-Regulated Products Covered by This Final Rule-Making, 2015.

(non-electronically) using paper format at the port of entry and the nearest FDA office would not be affected by this final rule. Regardless of electronic or paper submission, the requirements for admissibility by FDA would remain the same. Also note that additional information may still be requested on a case-by-case basis by FDA to make an import entry decision.

[12] Even if the data is submitted electronically, other factors may influence FDA's decision to request additional information to help the Agency make an imports admissibility decision. This is because some products could be on import alert, scheduled for sampling, have high risk factor scores, etc. In addition, incorrect data could be submitted to FDA or correct data submitted incorrectly, resulting in longer total processing time by FDA in part because such cases require manual review. [13] FDA's Prior Notice rule mandates certain data elements that must be submitted prior to food cargo arrival to the port of entry (see 21 CFR 1.281). Foods other than LACF, ACF, and food contact substances are not covered by this final rule.

[13] FDA's Prior Notice rule mandates certain data elements that must be submitted prior to food cargo arrival to the port of entry (see 21 CFR 1.281). Foods other than LACF, ACF, and food contact substances are not covered by this final rule.

Product Category	Annual Number of Import Lines	Import Lines, Percent of FDA Grand Total	Percent of Lines Submitted in ACS without Voluntary Data
Animal Drugs	59,269	0.2%	76%
Biological Products	156,806	0.5%	91%
Cosmetics	3,028,991	8.5%	99%
Human Drugs	691,367	2.0%	23%
Food Contact Substances	1,554,494	4.5%	81%
LACF, ACF	380,140	1.1%	28%
Medical Devices	16,790,971	47.4%	2%
Radiation-Emitting Electronic Products	957,527	2.7%	26%
Tobacco Products	16,056	0.1%	100%

Table 3 summarizes voluntary ACS data submission practices by industry. It shows that based on 2015 FDA internal data [1], the share of lines submitted without any of the voluntary information was as low as 2 percent for medical devices and as high as 99 percent for cosmetics (Table 3). This means that at least some voluntary data was provided by filers for nearly 98 percent of all medical device import lines that represented about half of all FDA import lines (16.7 million out of 35.4 million lines) or about 71 percent of import lines covered by this final rule (Table 3) [6]. In 2015, voluntary data submission for other products varied from 0 to 77 percent depending on product category (Table 3).

Table 4. The Number of Elements Mandated by The Final Rule and the Number of Elements that Would Require Additional Compliance Time, by Product Category

Product Category	Data Elements

	new	in ACS and will be mandated in ACE[14]	mandated by other FDA rules or supplied voluntary	maximum number that would need additional compliance time
Animal Drugs	1	7	4	4
Biologics	2	8	4	6
Cosmetics	1	4	4	1
Human Drugs	1	7	4	4
Food Contact Substances	1	4	4	1
LACF, ACF	0	7	4	3
Medical Devices	1	11	7	5
Radiation-Emitting Electronic Products	1	18	18	1
Tobacco	2	4	4	2
Weighted Average Number of Data Elements	1	10	7	4

Table 4 shows that depending on product type, this final regulation mandates the submission of between 1 and 2 new data elements per import line; this is in addition to data elements that are now routinely submitted in ACE and used to be submitted in ACS. Not every element is required for each product in the same category and, as previously stated, some filers have been voluntarily submitting some data elements to FDA. For example, for medical devices between 2 and 3 data elements per import line have been voluntarily, routinely submitted to FDA via ACS [6]. We estimate that because some filers have been submitting some of these data elements voluntarily and would likely continue to do so, firms would need to prepare and submit into ACE information on 1 to 6 additional mandatory data elements per import line, with the best average estimate of up to 4 additional data elements (Table 4).

[14] In addition, the Intended Use Code data element was a CBP data element in ACS and will become FDA data element in ACE under this final rule. We do not include additional costs associated with submitting this data element in ACE because it is not new to the import process.

Under the baseline import process, after FDA's OASIS receives the electronic import entry information from CBP, FDA's risk-based electronic evaluation tool "Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting" commonly known as PREDICT quickly screens all electronic entries, evaluates potential risk associated with each product, and recommends whether a product should be further examined by FDA. Based upon the risk associated with the entry, FDA sends a message through OASIS to CBP via ACE back to the entry filer with a decision as to whether

(1) the product may proceed into the U.S.,

(2) additional information is required,

(3) an examination is required, or

(4) the shipment appears to be subject to refusal of admission.

Without changes to the data that was submitted in ACS and without finalizing this rule, FDA would have to continue using its own limited resources to collect and check the accuracy of the information voluntarily submitted by the importer and to collect any additional information that the Agency needs for making import admissibility decisions. The costs to FDA, therefore, would include the cost of continuing to link CBP's ACE to FDA's OASIS that started in 2014 and communicating to the industry about the changes, if any, related to the process of voluntarily submitting data to FDA. Such an approach would be inconsistent with Executive Order 13569, which directs a "transition from paper-based requirements and procedures to faster and more cost-effective electronic submissions to, and communications with, agencies" [7, p. 10658].

B. The Number of Projected Import Entries Over Time

According to FDA internal data, between FY 2010 and FY 2015, the total number of all import lines processed by FDA has increased by more than 50 percent, growing from approximately 21 million import lines in FY 2010 to over 35.4 million import lines in FY 2015 [8]. During the same period, the number of medical device import lines nearly doubled [8].[15] Given that between 2010 and 2015 the number of import lines processed by FDA has been steadily increasing by an average of about 10 percent per year, we expect that the annual number of import lines covered by this final rule will also continue increasing in the future.

According to FDA internal data, about 8.4 million import entries with 35.4 million import lines were processed by FDA in 2015 [9]. We estimate that out of 35.4 million import lines, about 23.1 million electronically-filed import lines will be affected by this final rule. We project that over the next 20 years, the annual number of FDA-regulated import lines and the number of lines covered by this final rule will 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, which would result in an average growth rate of about 3.3 percent per year (Table 5).[16]

Table 5. The Number of Import Lines Covered by This Regulation[17]

Year	The Number of Import Lines Covered by This Regulation	The Number of New Unique Product-Manufacturer Import Lines Covered by This Regulation
1	23,119,465	504,768
2	23,882,407	521,425
3	24,670,527	538,632

[15] Some of this increase is attributable to CBP's requirement on convenience kits for medical devices that are convenience kits or part of a convenience kit to be submitted as separate import lines.

[16] We estimate that growth rate of about 2.45 is consistent with the average Gross Domestic Product (GDP) growth rate of the U.S. economy for the 20-year period between 1995 and 2015 [28]. The future growth rate of import lines is unknown, so the Monte Carlo simulation is appropriate to set the range. We estimate the average growth rate of 3.3 percent per year as a mean of the Pert distribution with the following parameters: minimum growth rate of 0 percent per year, most likely growth rate of 2.45 percent per year, and maximum growth rate of 10 percent per year

[17] We generated the annual numbers of covered import lines using Monte Carlo simulations.

4	25,484,654	556,407
5	26,325,648	574,769
6	27,194,394	593,736
7	28,091,809	613,329
8	29,018,839	633,569
9	29,976,460	654,477
10	30,965,684	676,075
11	31,987,551	698,385
12	33,043,140	721,432
13	34,133,564	745,239
14	35,259,972	769,832
15	36,423,551	795,237
16	37,625,528	821,479
17	38,867,170	848,588
18	40,149,787	876,592
19	41,474,730	905,519
20	42,843,396	935,401

C. Option 1 - The Final Rule

Costs and Benefits of the Final Rule

After this rule is finalized, for each article that is subject to FDA regulation and covered by the final rule, importers must submit certain mandatory data elements in ACE in conjunction with CBP's import entry procedures. FDA will have access to these data elements to assist in import admissibility decisions for these products.

In order to comply with the final rule, importers of FDA-regulated commodities will need to complete certain start-up activities in the first year and maintain certain activities in subsequent years. We estimate that the costs to both domestic and foreign entities of complying with the final rule as based largely on the amount of additional time it will take firms to: 1) become aware of the requirements and learn what the requirements are; 2) have an administrative worker prepare the additional information required for each import line; 3) have the owner or

manager in charge confirm the information is correct[18]; and 4) have an administrative worker complete the entry declarations using software that is connected to ACE.[19] If importers find that it is more cost effective to delegate some of these tasks to brokers in exchange for a fee, they may choose to delegate all or part of this burden to brokers instead of completing all these steps by themselves.[20] Because baseline practices differ by importer, filer, and product type, we assume that the estimated additional time for each of these tasks is the *average* additional time per import line. We are not trying to assign responsibility for each task to importer, broker, or filer, but for ease of the presentation of this analysis, in describing our estimates below we make assumptions about who performs each of these tasks. Ultimately, it does not matter who performs each of these tasks, the person who is responsible for complying with this regulation is the importer.

Estimates of costs to industry from the final rule include costs of familiarizing themselves with this rule, preparing the required information, checking data quality, and completing and submitting the electronic entry submission. All cost estimates in this regulatory impact analysis are developed using industry interview data, internal FDA data, information provided by the public comments and best professional judgment [1], [6], [8], [10], [11], [12]. Table 6 summarizes annual costs to the industry. We estimate that in the first year the total cost of this final rule is between $25.5 million and $63.7 million per year[21], with the best estimate of $43.0

[18] Filers use certain privately-issued software that communicates back CBP refusal messages to confirm whether the information that is being submitted is correct. We estimate therefore that in cases when filers prefer relying on CBP refusal messages for quality checks, the time needed for this step is combined with the time for step 4 (to complete and submit the entry declaration in ACE) and spent on reading error messages communicated by the software and re-submitting the correct data instead of manager checking the entry. We also assume that in some cases this step is performed by importers before they forward data mandated by this final rule to their brokers.

[19] Because the costs of updating the existing software or purchasing a new one would fall under the cost of CBP's ACE regulation, we do not include these transition costs in this economic impact analysis.

[20] Currently, according to FDA internal data [9], about 97.7 percent of importers use brokers to file entries for FDA-regulated products that will be covered by this final rule.

[21] We generated upper and lower bounds using Monte Carlo simulations.

million; in the steady state, this best estimate cost is between $35.5 million and $63.7 million depending on the year (Table 6). Annualized over 20 years, these costs are $46.7 million per year with a 3 percent discount rate and $45.1 million per year with a 7 percent discount rate (Table 6).

Table 6. Total Costs of The Final Rule Over 20 Years (in $millions)

Year	Undiscounted Regulatory Costs				Present Value with Discount Rate[22]	
	Costs of reading the final rule	Costs of preparing data	Costs of quality check and submission into ACE	Total Cost by Year	3%	7%
1	$0.2	$0.7	$42.1	$43.0	$41.7	$40.2
2	$0.0	$0.7	$34.8	$35.5	$33.5	$31.0
3	$0.0	$0.7	$35.9	$36.7	$33.6	$29.9
4	$0.0	$0.8	$37.1	$37.9	$33.7	$28.9
5	$0.0	$0.8	$38.3	$39.1	$33.8	$27.9
6	$0.0	$0.8	$39.6	$40.4	$33.8	$26.9
7	$0.0	$0.8	$40.9	$41.8	$33.9	$26.0
8	$0.0	$0.9	$42.3	$43.1	$34.1	$25.1
9	$0.0	$0.9	$43.7	$44.6	$34.1	$24.2
10	$0.0	$0.9	$45.1	$46.0	$34.2	$23.4
11	$0.0	$0.9	$46.6	$47.5	$34.3	$22.6
12	$0.0	$1.0	$48.1	$49.1	$34.4	$21.8
13	$0.0	$1.0	$49.7	$50.7	$34.5	$21.1
14	$0.0	$1.0	$51.4	$52.4	$34.6	$20.3
15	$0.0	$1.1	$53.1	$54.1	$34.7	$19.6
16	$0.0	$1.1	$54.8	$55.9	$34.8	$18.9
17	$0.0	$1.2	$56.6	$57.8	$34.9	$18.3
18	$0.0	$1.2	$58.5	$59.7	$35.1	$17.7

[22] Present values are calculated for each year at the end of the period. Present value adjusts for the time value of money with a 3 or 7 percent discount rate (i.e., costs incurred in future years have a lower present value than costs incurred in year 1).

19	$0.0	$1.2	$60.4	$61.6	$35.2	$17.0
20	$0.0	$1.3	$62.4	$63.7	$35.3	$16.5
Total Years 1 to 20				$960.6	$694.4	$477.3
Annualized Total Over 20 Years					$46.7	$45.1

The final rule will also update FDA's current regulations on imports by clarifying that FDA can electronically notify owners or consignees that the article offered by them for import into the U.S. may be subject to refusal of admission and/or that the article is a drug that may be subject to administrative destruction. Thereby, this regulation will streamline FDA's ability to communicate and respond to importers faster and allow FDA to better use its limited resources.

We estimate that the potential benefits to both FDA and the industry will occur because of the potentially reduced timeframe to process import entry declarations, fewer imported products being held and a shorter timeframe between the time of entry transmission and a final admissibility decision by FDA as a result of increased efficiency in FDA's entry decision process. Because of limited industry data and uncertainty we are unable to quantify these benefits, but expect them to be positive. Benefits to the general public that we are unable to quantify at this time will result from FDA-regulated imports reaching the U.S. consumers faster and from fewer non-compliant imports reaching the U.S. consumers, which will potentially improve the overall safety of FDA-regulated imports on the U.S. market and thereby have a positive impact on health of the general public. Benefits to the industry in the form of cost savings that we are similarly unable to quantify will also arise from increased efficiency of the import process. This is because revising certain sections of the 21 CFR Chapter I provides more clarity to the industry about certain aspects of the overall import process of FDA-regulated products.

In addition, benefits that would range between $2.6 million and $43.3 million per year[23], with the best estimate of $21.0 million per year in the form of cost saving to both the industry and FDA would arise because with this final rule FDA would simplify and speed up the notification process on certain FDA actions taken by the Agency under section 801 of the FD&C Act by allowing electronic notification of the owner or consignee (Table 7). Annualized over 20 years, partially quantifiable benefits are $21.0 million per year with a 3 percent discount rate and $21.0 million per year with a 7 percent discount rate (Table 7). FDA acknowledges the uncertainty of these calculations.

Table 7. Quantifiable Benefits of The Final Rule Over 20 Years (in $millions)

Year				Present Value with Discount Rate	
	Benefits to the industry from electronic notification of certain FDA actions	Benefits to FDA from electronic notification of certain FDA actions	Total Quantifiable Benefits by Year	3%	7%
1	$20.4	$0.7	$21.0	$20.4	$19.6
2	$20.4	$0.7	$21.0	$19.8	$18.4
3	$20.4	$0.7	$21.0	$19.2	$17.2
4	$20.4	$0.7	$21.0	$18.7	$16.0
5	$20.4	$0.7	$21.0	$18.1	$15.0
6	$20.4	$0.7	$21.0	$17.6	$14.0
7	$20.4	$0.7	$21.0	$17.1	$13.1
8	$20.4	$0.7	$21.0	$16.6	$12.2
9	$20.4	$0.7	$21.0	$16.1	$11.4
10	$20.4	$0.7	$21.0	$15.6	$10.7
11	$20.4	$0.7	$21.0	$15.2	$10.0
12	$20.4	$0.7	$21.0	$14.7	$9.3
13	$20.4	$0.7	$21.0	$14.3	$8.7

[23] We generated upper and lower bounds using Monte Carlo simulations.

14	$20.4	$0.7	$21.0	$13.9	$8.2
15	$20.4	$0.7	$21.0	$13.5	$7.6
16	$20.4	$0.7	$21.0	$13.1	$7.1
17	$20.4	$0.7	$21.0	$12.7	$6.7
18	$20.4	$0.7	$21.0	$12.3	$6.2
19	$20.4	$0.7	$21.0	$12.0	$5.8
20	$20.4	$0.7	$21.0	$11.6	$5.4
Total Years 1 to 20			$420.5	$312.8	$222.7
Annualized Total Over 20 Years (Quantifiable Only)				$21.0	$21.0

Costs of the Final Regulation

Rule Familiarization (one-time cost)

The costs of becoming aware of the requirements of the final rule arise because importers and filers must familiarize themselves with rule provisions. This administrative cost may include some or all of the following: reading the rule[24], understanding the reporting requirements, consulting with specialists if necessary, familiarizing themselves with the revisions of privately-developed computer software that are related to this final rule, determining how to best meet rule requirements and communicating these requirements to clients and workers. An entry filer would need to complete these activities in order to determine which specific data elements listed in the final rule are required for submission into ACE as a part of an import entry declaration for every FDA-regulated product covered by this final rule. If a filer is a broker and not an importer itself, then a broker needs to be prepared to communicate this information to his clients that

[24] We have found that most filers may not take a long time to read this final rule to familiarize themselves with changes relating to imports to determine how those changes would apply to an article being imported or offered for import [10]. As a part of their usual and customary business practice, many brokers rely on software and CBP messaging and on FDA seminars to tell them what data elements are needed for each import entry declaration. Furthermore, the final rule is fairly short, not complex, and does not require a big number of data elements to be submitted in ACE for an FDA-regulated product. Most of the data elements required by the final rule are currently collected on a voluntary basis, so filers should be familiar with them.

would be impacted by this final rule. These costs are one-time costs that are estimated on a per-firm basis and will be incurred during the first year.

Currently, most entry declarations for FDA-regulated imports are filed by custom brokers rather than importers. Based on FDA's internal data [1], we estimate that in 2015 about 97.7 percent of importers used customs brokers to file import entry declarations. This suggests that the majority of importers would rely on the custom brokers to read and understand this final regulation and tell them what is needed to comply with this final rule. All future importers of FDA-regulated commodities would experience these costs upon entering the reporting community, meaning before they offer cargo for import into the U.S. We assume that new entrants into the system would still primarily rely on the already knowledgeable customs brokers to communicate to them the requirements of this final rule and to simply tell them the information required for ACE. We attribute these costs to new entrants as a usual and customary start-up business cost and do not include them in this analysis.

Administrative costs of familiarization with the final rule are summarized in Table 8. We estimate that, for each of the 3,667 import entry filers, one operations manager would spend between 0 and 1 hour with the best estimate of 30 minutes (0.5 hour) to review, assess, and communicate to other colleagues the requirements of this final rule. The base wage rate of $57.44 is taken from the May 2015 BLS Occupational Employment Statistics for general and operations managers [12] and increased by 100 percent to include overhead costs and benefits. When doubled, the overhead-adjusted wage rate for a manager, who could be the owner, operator, or agent in charge, is $114.88. We estimate that to become familiar with the requirements of this regulation, a total of 3,667 filers, including 959 importers (= 41,703 importers x (100-97.7) percent), would in total spend between 579 and 3,088 hours, with the best

estimate of 1,834 hours, at a total cost of between $0.07 million and $0.35 million, with the best estimate of $0.21 million (Table 8).[25] This results in an average burden of between 0.16 hours and 0.84 hours per filer at a cost of between $18 and $97, with the best estimate of $57 per filer (Table 8).

Table 8. Administrative Costs of Familiarization with the Final Rule (One Time)

	Number of Responders	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm
First Year	3,667	One time	0.5	1,834	$114.88	$0.21	$57

Preparing the Required Information

In the first year, for any import lines that represent unique product-manufacturer combinations, an importer will need to establish the internal data sources and documents that contain information mandated by this final rule and to prepare this information for submission into ACE or for his broker.[26] In 2015, for products that will be covered by the final rule there were about 504,768 import lines that represented unique product-manufacturer combinations, or about 2.2 percent of all import lines [1]. This share of 2.2 percent represents the share of new unique import lines for which we estimate each year a filer will need to prepare information required by this final rule for submission into ACE.

Every year the additional time spent preparing all of the information mandated by the final rule would vary depending on data element, product type, importers' and brokers' internal

[25] We generated upper and lower bounds using Monte Carlo simulations.
[26] The information required to be provided to ACE by the customs broker or directly by the importer may be newly mandated for submission into ACE, but it may be information already required by FDA for other purposes and covered by a variety of other regulatory recordkeeping requirements.

business practices related to maintaining imports entry data [10] and filer's baseline submission practices. We assume that preparing information on some data elements for the first time, such as e-mail address, can on average take as little as a few seconds, while locating and providing information on other data elements may require several minutes. We assume that it would take one administrative worker between 1 and 4 additional minutes[27] with the best estimate of 2.33 minutes (range of 0.0167 to 0.067 hours with the mean estimate of 0.039 hours) per unique product-manufacturer import line to locate and gather all the information[28] required by this final rule (Table 9).

For the purpose of this analysis, we estimate that for each unique product-manufacturer import line covered by this final rule, this additional time would be spent by an administrative worker on locating the sources of the data; preparing the required information from multiple sources for entering into ACE, including reaching out to manufacturers if necessary; logging into the system; entering the required information or updating the already existing information in that firm's internal database; and, if applicable, sending the updated database to the broker. Once this information is gathered and entered into the filer's internal databases, it does not need to be gathered again for a similar subsequent shipment of the same product produced by the same manufacturer (we assume this is the case for about 97.8 percent of all import lines covered by this final rule); this duplicative information will already be in the existing importer's or broker's databases and readily available to them.

[27] These lower and upper bounds were estimated using the weighted average from Table 4 for the number of data elements that would require additional compliance time and the assumption that it would take 1 minute per data element to complete this task.

[28] The expectation is that importers will have all of this information readily available to them and will not have to contact manufacturers or other entities to obtain these data elements. Importers will also provide all of this information to brokers if they hire brokers to file entry declarations for them.

Table 9 shows that we estimate that in the first year the average frequency of filing unique product-manufacturer import entry declarations of FDA-regulated products covered by this final rule will be about 12 import lines per importer (= (23.1 million electronically-filed import lines x 2.2 percent) / 41,703 importers). The base wage rate of $17.47 per hour are taken from the May 2015 BLS Occupational Employment Statistics for administrative workers [13] and increased by 100 percent to $34.94 to include overhead costs and benefits. We estimate that the total cost of preparing information mandated by this final rule for ACE entry for new unique product-manufacturer combination import lines would range between $0.4 million to $1.0 million[29], with the best estimate of about $0.7 million in the first year and between $0.7 million and $1.3 million per year in years two through twenty (Table 9).

Table 9. Cost of Preparing Information for Import Entry Filing (unique import-manufacturer import lines only), in millions

Year	Number of Respondents	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in millions	Cost per firm
1	41,703	12	0.471	19,630	$34.94	$0.7	$16
2	41,703	13	0.486	20,278	$34.94	$0.7	$17
3	41,703	13	0.502	20,947	$34.94	$0.7	$18
4	41,703	13	0.519	21,638	$34.94	$0.8	$18
5	41,703	14	0.536	22,352	$34.94	$0.8	$19
6	41,703	14	0.554	23,090	$34.94	$0.8	$19
7	41,703	15	0.572	23,852	$34.94	$0.8	$20
8	41,703	15	0.591	24,639	$34.94	$0.9	$21
9	41,703	16	0.610	25,452	$34.94	$0.9	$21
10	41,703	16	0.630	26,292	$34.94	$0.9	$22
11	41,703	17	0.651	27,159	$34.94	$0.9	$23
12	41,703	17	0.673	28,056	$34.94	$1.0	$24
13	41,703	18	0.695	28,982	$34.94	$1.0	$24
14	41,703	18	0.718	29,938	$34.94	$1.0	$25

[29] We generated upper and lower bounds using Monte Carlo simulations.

15	41,703	19	0.742	30,926	$34.94	$1.1	$26
16	41,703	20	0.766	31,946	$34.94	$1.1	$27
17	41,703	20	0.791	33,001	$34.94	$1.2	$28
18	41,703	21	0.817	34,090	$34.94	$1.2	$29
19	41,703	22	0.844	35,215	$34.94	$1.2	$30
20	41,703	22	0.872	36,377	$34.94	$1.3	$30
Total				**543,857**		**$19.0**	

Quality check of data and ACE submission

The final rule would make the submission of certain data elements in ACE mandatory. To ensure the accuracy of the information submitted in ACE for all import lines of FDA-regulated products covered by this final rule, we estimate that either the importer or the filer would perform an additional verification step prior to or at the time of submitting these data elements into ACE – data quality checks. This step would apply to all data elements listed in the final rule regardless of whether an importer was previously submitting some of these data elements into ACS. Instead of relying on human verification of the data by managers all the time, some filers may rely on automated, reject messaging from CBP or FDA to identify missing or incorrect data. In these cases, we estimate that in lieu of spending time on quality checks by managers this time is spent on resubmitting the accurate information into ACE. We also estimate that for each import line covered by the final rule, one administrative worker would need to use special software linked to CBP's ACE to enter and electronically submit all the information mandated by this final rule. The costs associated with purchasing and maintaining this special software that importers and other filers use for importing is part of the baseline, so we do not include the costs of such software in this analysis of this final rule.

Based on FDA internal data [1], we estimate that in the first year, the frequency of import entry filings covered by this final regulation will be 6,305 import line entry declarations per filer

(= (23.1 million import lines) / 3,667 filers), or about 121 import lines per week (Table 10). In the subsequent years, the annual frequency would range between 6,513 and 11,684 import entry declarations filings (Table 10). The information and therefore time required for each import line would vary based on the total number of required data elements, product category, filer's and importer's current baseline practice and the type of software[30] they use to file ACE entries.

While quality checks are typically performed by operation managers, we estimate that administrative workers are the ones submitting information into ACE. We use labor cost of $74.91 (= (114.88 + 34.94) / 2), which is the average between the cost for general and operations manager and the cost for administration worker. We estimate that in the steady state it would take one operations manager and one administrative worker on average between 0.5 and 2 minutes in total, with the best estimate of 1.2 minutes in total per import line to conduct quality check of the data elements mandated by this final rule and to submit an entry into ACE (Table 10). We also assume that in the first year some learning and adjusting to the new system for filing newly-mandated by FDA data elements will be involved for some filers and that it would take filers between 0 and 50 percent[31] more time to complete this task in the first year. In total, we estimate that in the first year it would cost between $25.0 million and $62.3 million[32] with the best estimate of $42.1 million (Table 10) to complete this task of quality check and entry submission; in years 2 to 20 the total costs of this task would range from $20.7 million to $92.3 million[33], with the best estimate of between $34.8 million and $62.4 million.

[30] We take into consideration that some software stores previous information and can automatically populate some information from previous similar import entry filings [10].
[31] We received several public comments saying that the cost to file FDA entries in ACE has increased for some filers by 50 percent compared to ACS entry filing. In response to these comments we, therefore, increase the upper threshold from 25 percent to 50 percent in estimating that in the first year it would take filers more time to complete this task.
[32] We generated upper and lower bounds using Monte Carlo simulations.
[33] We generated upper and lower bounds using Monte Carlo simulations.

Table 10. Cost of Quality Checks and Submitting Data into ACE							
Year	Number of Respondents	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm
1	3,667	6,305	153	561,931	$73.43	$42.1	$11,479
2	3,667	6,513	127	464,380	$73.43	$34.8	$9,486
3	3,667	6,728	131	479,705	$73.43	$35.9	$9,799
4	3,667	6,950	135	495,535	$73.43	$37.1	$10,123
5	3,667	7,179	140	511,888	$73.43	$38.3	$10,457
6	3,667	7,416	144	528,780	$73.43	$39.6	$10,802
7	3,667	7,661	149	546,230	$73.43	$40.9	$11,158
8	3,667	7,914	154	564,255	$73.43	$42.3	$11,527
9	3,667	8,175	159	582,876	$73.43	$43.7	$11,907
10	3,667	8,444	164	602,111	$73.43	$45.1	$12,300
11	3,667	8,723	170	621,980	$73.43	$46.6	$12,706
12	3,667	9,011	175	642,506	$73.43	$48.1	$13,125
13	3,667	9,308	181	663,708	$73.43	$49.7	$13,558
14	3,667	9,615	187	685,611	$73.43	$51.4	$14,006
15	3,667	9,933	193	708,236	$73.43	$53.1	$14,468
16	3,667	10,261	200	731,607	$73.43	$54.8	$14,945
17	3,667	10,599	206	755,751	$73.43	$56.6	$15,439
18	3,667	10,949	213	780,690	$73.43	$58.5	$15,948
19	3,667	11,310	220	806,453	$73.43	$60.4	$16,474
20	3,667	11,684	227	833,066	$73.43	$62.4	$17,018
Total				**12,567,297**		**$941.4**	

Benefits of the Final Regulation

The benefits that would result from this final rule can be divided into the following categories: (a) potential cost savings to industry as a result of FDA's improved ability to process entries in a more timely and effective manner because of newly-mandated ACE data elements; (b) potential cost savings to FDA as a result of more efficient processing of entries resulting from

the availability of enhanced data set; (c) potential benefits to the general public from a more efficient import process because of new required ACE data elements; (d) potential cost savings to the industry from a better informed import process, and (e) cost savings to FDA and industry from electronically providing notices of certain FDA actions. Table 11 summarizes these benefits. We cannot fully quantify all benefits; we quantity part of the cost savings to industry and FDA and describe the other benefits.

Table 11. Summary of Benefits from the Final Rule

Benefit	Who benefits	Benefits	Description
Cost savings to industry from FDA's improved ability to better streamline the import entry admissibility process due to the availability of the required ACE data	Industry	Not quantified	Potential time reduction for processing import entry declarations by FDA; potentially improved predictability of the import process; potentially fewer and shorter timeframes for imported products being held pending a final admissibility decision and a decrease in the corresponding costs.
Cost savings to FDA from FDA's improved ability to better streamline the entry admissibility process due to the availability of the new ACE data	FDA	Not quantified	More efficient use of internal resources
Health-related benefits to the general public and benefits to industry from a more efficient import process	The general public, industry	Not quantified	Potentially fewer recalls of imported products, reduction of counterfeit and misbranded products on the U.S. market
Cost savings from a better informed import process	Industry	Not quantified	Decreased ambiguity because of a better defined the *owner or consignee*

			term and the clarifications related to notice of sampling, notice on refusal of admission, and notice of destruction of drugs
Cost savings to FDA from electronically providing notices of hearing on refusal of admission or destruction	FDA, industry	Partially quantifiable, $21.0 million (range $2.60 million to $43.4 million)	Warehousing and storage cost savings for importers; more efficient use of internal resources.

a) ***Cost savings to industry from FDA's improved ability to better streamline the imports entry review process due to the availability of the required ACE data elements***

We expect that the benefits from the final rule in a form of cost savings to both FDA and industry would include time savings. These potential time savings would be possible because of FDA's better use of its electronic screening capacity made possible by the new data submitted by import entry filers into ACE. We anticipate the following economy-wide cost savings to FDA and industry from new ACE data aiding FDA's ability to more efficiently process import entry declarations:

- Potential reduced time for processing import entry declarations by FDA;
- Potentially fewer imported products being held;
- Potentially shorter timeframe between the time of entry transmission and a final admissibility decision by FDA because of shorter processing time to investigate and release compliant products after manual review.

FDA typically uses the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), an electronic screening tool for its import operations. This tool helps FDA take a risk-based approach to admissibility decisions and more effectively utilize its limited human capital resources. After an import entry filer submits an import entry

declaration in ACE and all the required information is sent to FDA, FDA processes the entry through OASIS and PREDICT and reviews the entry. Every electronic entry is automatically screened by the system, and may also be reviewed manually by an FDA entry reviewer. Once FDA makes an initial or final admissibility decision on the entry, the disposition message is sent back through ACE to the filer. This message indicates FDA's decision on whether: (a) the product may proceed into U.S. commerce, (b) additional information is required, (c) an examination is required, or (d) the shipment appears to be subject to refusal of admission. According to FDA's internal data [1], in 2015 a system 'may proceed' decision was issued in between 3 percent to 72 percent of the entry declarations, depending upon the product type. More information from importers and more accurate data would allow FDA to potentially increase the average number of system 'may proceed' decisions. By accurately providing FDA with the information on ACE data elements required by this final rule, most importers may potentially be able to increase the probability of receiving 'may proceed' from FDA or receiving it faster than under ACS, potentially reduce the probability of having to submit additional information to FDA after the initial submission, potentially reduce the probability of a product being held by FDA, and/or potentially reduce the length of a detention period if it occurs, but that will be based on the number and types of reasons for which the article was detained.

Currently, for importers and other industry participants that don't get system 'may proceed' for a product, by default there will be additional time needed to process the entry prior to a final admissibility decision by FDA. By complying with this final rule and submitting accurate and complete entry data to FDA, importers and filers may be able to potentially reduce or eliminate the extended time period between entry transmission and a final admissibility decision, which would result in cost savings. These cost savings represent the opportunity cost

of the capital needed to import these products into the U.S. We do not have the information to estimate whether as a result of this final rule getting a system 'may proceed' decision would occur for most entries or only for some entries. These cost savings reflect profits and sales that would no longer be lost because of possibly faster 'may proceed' decisions; there may be additional cost savings from possibly reduced warehousing and personnel expenses that we are similarly unable to quantify at this time because of the lack of data about certain practices and uncertainty about future changes in the usual and customary business practices.

Potentially having a more predictable import process may also be important for importers and other businesses that are involved in the import process.[34] This is because some importers often base their usual and customary business practices on a promise to their clients of either fast or guaranteed delivery within a specified time frame. Uncertainty surrounding import admissibility reduces the chance of fulfilling such obligations to their clients, negatively impacts their usual and customary business practices, and reduces their ability to increase their market share and attract more clients. Businesses typically value their usual and customary business practice and have incentives to protect and improve upon it. The changes to the data elements required for import entry under this final rule, we believe, will allow businesses to improve upon their usual and customary practices, but we are unable to quantify these process improvements.

b) Cost savings to FDA from FDA's improved ability to better streamline the imports entry review process due to the availability of the required ACE data elements

[34] The import system is complex. In addition to CBP and FDA, importers typically have to deal with other entities involved in this process such as land, ocean, and air carriers; terminals; warehousing facilities, etc. Currently, faster FDA import entry approval, for example, receiving 'may proceed' in 3 days rather than 4 days does not necessarily always make a difference to some importers that import cargo by sea. Even if the cargo is cleared by CBP and FDA, it may still be at sea and importers have to wait for it to arrive to the port of entry [10]. However, to some importers that use other transportation modes such as air or truck modes to import their cargo timing is often critical to their operation as arrival is imminent. With a potentially more predictable import processing time importers could adjust their shipping schedules to better match the cargo delivery date to an estimated entry release date.

The volume of imported FDA-regulated products has increased enormously over the past 20 years. Yet, FDA's own work force that is responsible for ensuring imports safety and admissibility review remained largely unchanged. For example, in just 5 years between 2010 and 2015, the total number of imported lines increased from 21 million to 35 million import lines, or by about 60 percent [8]. The number of imported medical devices nearly doubled, going from fewer than 8.8 million import lines in 2010 to 16.8 million lines in 2015 [1], [8].[35] Overall, according to FDA's internal data, by 2015 medical devices accounted for about half of all import lines regulated by FDA [9]. However, FDA has a limited border screening capacity and physically examines less than 2 percent of imports [14, p. 43]. Having a more efficient automated imports admissibility process such as ACE and additional information for risk-based entry decisions would allow FDA to more efficiently screen imports in the face of the Agency's limited resources and increasing import volume.

In this environment of constantly increasing volume of incoming imports, FDA is charged with the responsibility of ensuring the safety and efficacy of FDA-regulated products and of making the admissibility decisions on import products that it regulates. In order to successfully and efficiently complete this task in a reasonable time period and without significantly increasing the number of FDA employees, FDA needs sufficient and accurate product, facility, and affirmation of compliance data to make a more informed risk-based decision about import admissibility. FDA continues to communicate to the importing industry that accurate firm, product, and compliance data are critical to expedite admissibility review [15].

[35] Some of this increase is attributable to CBP's requirement on convenience kits for medical devices that are convenience kits or part of a convenience kit to be submitted as separate import lines.

Data errors in import entry declarations submitted via ACS often included errors related to improper FDA product code, inaccurate FDA firm information (manufacturer, shipper, and consignee), and inadequate affirmation of compliance data. For example, FDA's Division of Import Operations estimated that in fiscal year 2013, over 25 percent of medical device import lines had one or more data errors in their import entry declarations submitted via ACS [15]. In a number of cases, data were not transmitted at all; for example, submissions lacked registration and listing information, or were not transmitted correctly [15]. Additionally, in a number of cases the submitted data did not match FDA databases; for example, listing information was not valid, or data were not associated with the same firm or product [15]. Missing or inaccurate data submitted to FDA often leads to delays in the admissibility review process because FDA employees must manually review entry declarations.

Moreover, even when the FDA received some of the data but other data elements were missing, the entry required manual review in order to make an admissibility decision. For example, without the "intended use" data element that FDA would now have access to through CBP's ACE, for a large percentage of regulated products FDA was unable to determine (without manual review) if brand name, listing, or registration information on the product was needed in order to make a final admissibility decision. Some of the other data elements that would be mandated by FDA in ACE are not new, but there was no standardized way that this information was provided to FDA in ACS.

With this final rule, therefore, FDA has decided to identify the information that will allow it to use a more effective, streamlined process targeting the highest risk import entries, thus potentially resulting in fewer detentions and fewer and shorter delays for lower-risk entries. This means that the FDA could more effectively use its own resources and concentrate its efforts on

high-risk imports. We are unable to quantify exact resource savings to the Agency because of uncertainty surrounding import volumes and incoming data quality, but expect that finalizing this rule would result in zero or positive cost savings to FDA.

c) Health-related benefits to the general public and benefits to industry from a more efficient import process

By finalizing this rule, FDA gives importers greater responsibility of providing the Agency with the information necessary for determining the admissibility of the FDA-regulated products they offer for import into the U.S. The information that importers will need to generate and that filers will be required to submit into ACE will help FDA improve FDA's risk-based screening of ACE import entries. This will reduce the likelihood that a non-compliant FDA-regulated imported product enters the U.S. commerce. According to FDA's internal data [1], in 2015 there were about 516 import recalls that involved 1,060 FDA-regulated products that belong to product categories that will be covered by this final rule. Implementation of this rule should potentially lead to fewer recalls of imported products, which may be costly to both industry and the general public. At this time we are unable to quantify these health-related benefits because multiple factors influence the outcome; for example, imports may be recalled before the adverse impact on public health even occurs. Nevertheless, we expect these benefits to be positive.

The final regulation will help FDA reduce public health risk associated with FDA-regulated imports. For medical devices, for example, mandatory submission of the Device Listing Number in ACE will help prevent substandard and counterfeit devices entering the U.S. market from abroad. Medical devices manufactured for other countries may not, for example, be

equivalent to devices made for the U.S. market, may have labeling not in English, and may not meet labeling requirements for the U.S. market. All of these problems could affect patient safety.

d) Cost savings to the industry from a better informed import process

The import process for importers and other industry participants can be complex. These businesses, therefore, value efforts on the part of FDA to clarify the import admissibility process. By revising 21 CFR 1.90, the Agency shall provide the prompt notification directly to the owner or consignee, instead of sending the notice to the collector of customs that would then send the notice to the owner or consignee. By making revisions to clarify the term owner or consignee and the notices of sampling, this final rule and FDA decrease ambiguity and provide additional information to the industry that increases the clarity of FDA's import admissibility process. We are unable to quantify the value that the importing industry places on having a more clear and therefore more efficient import process because of these revisions of 21 CFR Chapter I, but expect these benefits to be positive [16].

e) Cost savings related to revisions of 21 CFR Chapter I related to hearings of refusal of admission or destruction

Additional cost savings from this final rule would arise from allowing FDA to electronically notify the owner or consignee of an FDA action related to hearing on refusal of admission or administrative destruction. Currently, 21 CFR 1.94 states that FDA shall give a written notice to the owner or consignee. Such notice provides the owner or consignee of an FDA-regulated article being imported or offered for import into the United States with

opportunity to present testimony to the Agency prior to refusal of admission of an FDA-regulated article and/or prior to administrative destruction of certain refused drugs.

Cost savings will arise in the form of the time and resource savings to both importers and FDA. FDA would save some resources such as paper, envelopes, labels, stamps, ink and electricity for printers because FDA employees would not need to print, put into an envelope, label, stamp, and place these written notices in the mailbox. In addition, FDA will also save labor hours because performing these tasks takes time, while sending notices electronically happens virtually instantly and looking up the email address of an owner or consignee takes only seconds. These additional labor hours and resources are difficult to quantify but may be saved by FDA compliance officers who create such notices and by FDA's mail-handling facility personnel who would handle the reduced outgoing mail volume.

Savings to the industry may occur because of a shorter wait time before owners and consignees receiving a notice of FDA actions to refuse and/or subject certain imports to administrative destruction. Compared with receiving such notice by mail, which takes typically 5-6 days [17], electronic notice provides virtually instant notification. Receiving a notice of potential refusal or destruction sooner than before, for example, would allow owners and consignees to start preparing their testimony for FDA sooner because of the eliminated mail delivery period, or in some cases to make a decision sooner on whether to request reconditioning of their cargo. In some cases, this may also mean shorter cargo storage time at warehouses for those owners and consignees that would be able to present their testimony to FDA several days sooner than before because of time savings from the eliminated mail delivery period. The warehouse costs would differ depending on product type, temperature requirements, and product volume or size. We estimate that on average these time savings will average 5.5 days, which we

convert to warehouse storage cost savings for those owners and consignees. The cost of the space needed to store each import product line may be $50-$150 per day for typical shipments [18], with the best cost estimate of $100.[36]

According to FDA internal data [1], in 2015 there were 74,022 import lines that received a notice of potential refusal; some of these lines were later refused admission and issued an FDA notice of refusal of admission after the hearing period expired. In addition, 10,591 cases that would have potentially required a notice of potential destruction of drugs if FDA had finalized the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule before 2015 [19].[37,38] Because FDA intends to combine into a single notice the notice related to potential refusal of admission with the notice of potential destruction for drugs under the FD&C Act, we only count the number of notices related to potential refusal of admission in our estimates of cost savings. Under the assumption that about 50 percent of imports that receive such notices are already in ports (a mean of a uniform distribution of 0 and 100 percent), then cost savings to the entire industry from reduced storage costs are between $2 million and $43 million per year[39], with the best estimate of $20.4 million per year (5.5 days x $100 cost per day x 74,022 entities x 50 percent of cases = $20.4 million). We acknowledge uncertainty surrounding this assumption and the lack of data that is available to us to produce the exact cost savings estimates to those owners and consignees that would receive a notice from FDA by electronic mail instead of regular mail. In the PRIA, we requested comment on possible cost savings (in dollars) from revisions to 21 CFR 1.94 that would allow FDA to electronically notify

[36] Costs may vary greatly depending on location of goods, port, volume of goods, etc. Movement of goods is controlled by CBP, not FDA. Once an importer gets a conditional release from CBP, the importer can move the product to its own warehouse, as long as the goods are held intact pending FDA admissibility decisions.
[37] The RIA for the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule doesn't account for electronic notification [26].
[38] We do not have any information to make an assumption on whether the number of these cases would increase or decrease in the future.
[39] We estimate upper and lower range using Monte Carlo simulations.

the owner or consignee of a hearing on refusal of admission or administrative destruction, but received no such comments.

Additional cost savings to FDA would include time saved by issuing notices electronically. We estimate that currently it takes one FDA[40] employee between 5 and 7 minutes [17] to issue and print a written notice and either hand it over to the owner or consignee, or to place into an envelope, label, stamp it, and put it in the mail. After the final rule is implemented, we estimate it will take the same worker on average 1 minute to look up the email address for the owner or consignee and send a notice electronically. We estimate therefore that this will result in an average of 5 minutes savings per notice. In 2015, there were 74,022 imports cases that required a notice of action and 10,591 cases that would have potentially required a notice of potential destruction of drugs if FDA would have finalized the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule before 2015 [1], [19].[41] As already stated above, because FDA intends to combine into a single notice the notice related to hearing on refusal with the notice of administrative destruction for drugs under the FD&C Act, we only count the number of notices related to a hearing on refusals in our estimates of cost savings.

We assume that in some circumstances a hard-written copy notice may be necessary instead of an electronic notification and estimate that in 90 percent of cases such notice would be issued electronically. The cost of $120.19 per hour (= $250,000 / (52 weeks * 40 hours per week)) for one FDA employee is estimated using the annual per-employee cost information from FDA Budget Office [21]. The total estimated cost savings, therefore, are $0.7 million per year

[40] We use $250,000 as annual cost per one FDA employee that was provided to us by FDA Budget Office [21]. This number is based on annual salary, benefits, overhead (equipment, supplies, etc.) costs, information management and technology expenses, general overhead and administration costs, and rent and rent related expenses.

[41] The RIA for the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule doesn't account for electronic notification [26].

(74,022 notices x 0.90 x (6 minutes – 1 minute) / 60 minutes) x $120.19 hourly labor cost = $0.7 million).

D. Option 2 – All ACE Data Elements Listed in This Final Rule as Mandatory will be Voluntary Instead

Having no new mandatory data elements in ACE is Option 2 in our analysis. Under this option, FDA would request that the industry voluntarily submit all the data elements listed in this final rule. The total cost and the per firm cost of this option depends on whether businesses submit some or all of the voluntary information. A business has an incentive to only submit voluntary information into ACE if it believes that FDA values this voluntary information and such information would result in FDA making a faster automated 'may proceed' decision that would benefit the importer. This means that some importers and filers may be willing to pay more in terms of upfront expenses (by submitting more voluntary information) in order to potentially receive a faster 'may proceed' decision from FDA. Under Option 2 such businesses, therefore, will only bear the additional costs of learning about this regulation and to locate, prepare, enter and submit into ACE all or some of the data elements listed in this regulation if they anticipate the result will be a faster 'may proceed' FDA decision. Importers and filers will make this decision based on whether the anticipated additional gains from submitting more voluntary information are greater than the additional costs to do so.

Under Option 2 FDA will not be necessarily receiving all the information that can help ensure that imported cargo is as safe as domestically produced FDA-regulated products to the same extent it would under Option 1. This means FDA will not be able to make use of key technologies to target high risk products and more efficiently process import entries. This

option, therefore, likely would not potentially reduce the number of imported product recalls. For FDA this also means that unless the additional data is provided voluntarily by filers in ACE, the Agency would need to continue its inefficient practice of using its own resources to manually research the additional data often needed for import entry review and approval. In this environment of constantly increasing volume of incoming imports and without the sufficient ACE information, FDA may have difficulty efficiently issuing 'may proceed' admissibility decision for import cargo in a reasonable time given current Agency's resources.

E. Option 3 – Requiring all ACE Data Elements Listed in This Final Rule, but for Fewer Import Product Categories

Option 3 is a possible scenario where FDA would require data elements in ACE, but only for some product categories under the final rule. We consider the costs and benefits if only imported or offered for import Biological Products, Animal Drugs, Human Drugs, Radiation-Emitting Electronic Products and Medical Device products were covered by this final rule. Product categories such as Cosmetics, LACF, ACF, Food Contact Substances, and Tobacco Products would not be covered under Option 3. We now take the estimates from Option 1 and adjust them to account for fewer covered product categories.

This option slightly lowers the costs of this final regulation. We estimate that total annual costs for this option are $42.8 million in the first year and between $35.4 million and $63.4 million in years 2 to 20 (Table 12). Annualized over 20 years, costs for this option would be $46.5 million with a 3 percent discount rate and $44.9 million with a 7 percent discount rate (Table 12). Compared with the final regulation, annualized costs for Option 3 are lower by about $0.019 million at a 3 percent discount rate and by $0.018 million at a 7 percent discount rate.

Table 12. Total Costs of Option 3 (Fewer Covered Import Lines) Over 20 Years (in $millions)						
Year	Undiscounted Regulatory Costs				Present Value with Discount Rate	
	Costs of reading the rule	Costs of preparing, gathering data	Costs of quality check and submission into ACE	Total Cost by Year	3%	7%
1	$0.2	$0.7	$41.9	$42.8	$41.6	$40.0
2	$0.0	$0.7	$34.6	$35.4	$33.3	$30.9
3	$0.0	$0.7	$35.8	$36.5	$33.4	$29.8
4	$0.0	$0.8	$37.0	$37.7	$33.5	$28.8
5	$0.0	$0.8	$38.2	$39.0	$33.6	$27.8
6	$0.0	$0.8	$39.5	$40.3	$33.7	$26.8
7	$0.0	$0.8	$40.8	$41.6	$33.8	$25.9
8	$0.0	$0.9	$42.1	$43.0	$33.9	$25.0
9	$0.0	$0.9	$43.5	$44.4	$34.0	$24.1
10	$0.0	$0.9	$44.9	$45.8	$34.1	$23.3
11	$0.0	$0.9	$46.4	$47.4	$34.2	$22.5
12	$0.0	$1.0	$47.9	$48.9	$34.3	$21.7
13	$0.0	$1.0	$49.5	$50.5	$34.4	$21.0
14	$0.0	$1.0	$51.2	$52.2	$34.5	$20.2
15	$0.0	$1.1	$52.8	$53.9	$34.6	$19.5
16	$0.0	$1.1	$54.6	$55.7	$34.7	$18.9
17	$0.0	$1.1	$56.4	$57.5	$34.8	$18.2
18	$0.0	$1.2	$58.2	$59.4	$34.9	$17.6
19	$0.0	$1.2	$60.2	$61.4	$35.0	$17.0
20	$0.0	$1.3	$62.2	$63.4	$35.1	$16.4
Total Years 1 to 20				$956.8	$691.6	$475.4
Annualized Total Over 20 Years					$46.5	$44.9

Although this approach would slightly reduce the total cost of the final rule, it would also introduce inconsistency in the data that FDA would have in hand in case, for example, of a product recall of non-covered imports, and, therefore, introduce inefficiencies in the import entry review process. There would be fewer additional benefits under Option 3 than there would be

under Option 1. As in Option 1, we are unable to fully quantify these benefits. The benefits in a form of cost savings related to revisions of the 21 CFR 1.94 related to hearing on refusal of admission or administrative destruction and the cost savings to the industry from a better informed import process would remain the same as in Option 1.

F. Option 4 – Making All Data Elements Mandatory

Making all data elements mandatory in ACE is Option 4 in our analysis. This includes data elements that were collected in ACS and certain voluntary data elements that FDA would require in ACE. Under this option, FDA would mandate that the industry submits through ACE all the data elements currently listed in this final rule, along with all the voluntary and optional elements listed in FDA's ACE Supplemental Guide [22].

We now take the estimates in Option 1 and adjust them to account for more mandatory data elements, assuming that under Option 4, it would take importers and filers three times longer to comply with the regulation. We estimate that the total cost of this option would be $127.6 million in the first year and between $105.1 million and $188.5 million in years 2 to 20 (Table 13). Annualized over 20 years, costs for this Option 4 would be $138.2 million with a 3 percent discount rate and $133.4 million with a 7 percent discount rate, which is about $88.3 million to $91.5 million more than the costs for the final regulation (Table 13).

Table 13. Total Costs of Option 4 Over 20 Years (in $millions)

Year	Undiscounted Regulatory Costs				Present Value with Discount Rate	
	Costs of reading the rule	Costs of preparing, gathering data	Costs of quality check and submission into ACE	Total Cost by Year	3%	7%
1	$0.6	$0.7	$126.3	$127.6	$123.9	$119.3

2	$0.0	$0.7	$104.4	$105.1	$99.0	$91.8
3	$0.0	$0.7	$107.8	$108.5	$99.3	$88.6
4	$0.0	$0.8	$111.4	$112.1	$99.6	$85.5
5	$0.0	$0.8	$115.0	$115.8	$99.9	$82.6
6	$0.0	$0.8	$118.8	$119.6	$100.2	$79.7
7	$0.0	$0.8	$122.8	$123.6	$100.5	$77.0
8	$0.0	$0.9	$126.8	$127.7	$100.8	$74.3
9	$0.0	$0.9	$131.0	$131.9	$101.1	$71.7
10	$0.0	$0.9	$135.3	$136.2	$101.4	$69.3
11	$0.0	$0.9	$139.8	$140.7	$101.7	$66.9
12	$0.0	$1.0	$144.4	$145.4	$102.0	$64.5
13	$0.0	$1.0	$149.2	$150.2	$102.3	$62.3
14	$0.0	$1.0	$154.1	$155.1	$102.6	$60.2
15	$0.0	$1.1	$159.2	$160.2	$102.9	$58.1
16	$0.0	$1.1	$164.4	$165.5	$103.2	$56.1
17	$0.0	$1.2	$169.8	$171.0	$103.4	$54.1
18	$0.0	$1.2	$175.4	$176.6	$103.8	$52.3
19	$0.0	$1.2	$181.2	$182.5	$104.1	$50.5
20	$0.0	$1.3	$187.2	$188.5	$104.4	$48.7
Total Years 1 to 20				$2,843.9	$2,055.8	$1,413.3
Annualized Total Over 20 Years					$138.2	$133.4

Such an approach would increase the total cost of the final rule without significantly increasing the additional benefits. Currently, a business has an incentive to submit voluntary information into ACE if it believes that FDA values this voluntary information and that FDA would be enabled to make a faster 'may proceed' decision that would benefit an importer, meaning that some importers and filers may be willing to pay more in terms of upfront expenses in order to potentially receive a faster admissibility decision by FDA. Regardless of whether they value a faster admissibility decision, under Option 4 all businesses would have to bear the additional costs to learn about the final regulation and to prepare, enter, and submit into ACE all data elements listed in this final regulation and in the FDA's ACE Supplemental Guide [22], including elements that are voluntary and optional under the final rule. Given that not all businesses may value a faster FDA 'may proceed' decision because their cargo may still be days

away from the port of entry, Option 4 could impose an unnecessary burden on these businesses [10].

Under Option 4 FDA would be necessarily receiving more information than under Option 1. However, the added information that is voluntary under Option 1 and would become mandatory under Option 4 may not be powerful enough in further influencing the speed of the entry review process and the ability for the system to provide system 'may proceed' decision and, hence, would be likely of less value to FDA. Option 4, therefore, would not potentially reduce the number of imported product recalls as compared to the less costly Option 1. The benefits in a form of cost savings related to revisions of 21 CFR 1.94 to allow electronic notification of hearing on refusal of admission or administrative destruction and the cost savings to the industry from a better informed import process would remain for Option 4 the same as for Option 1.

G. Sensitivity Analysis

We estimate that the costs of the final regulation (Option 1) would be about $43.0 million in the first year and between $35.5 million and $63.7 million in years 2 to 20. The present discounted value of costs is $694 million at 3 percent discount rate and $477 million at 7 percent. At a 3 percent discount rate, the annualized costs of the final rule, discounted 20 years into the future, would be $46.7 million. For a discount rate of 7 percent, the annualized costs over 20 years would be $45.1 million. The benefits that we were able to quantify would be between $2.6 million and $43.4 million. The present discounted value of benefits that we were able to quantify is $312.8 million at 3 percent and $222.7 million at 7 percent. At a 3 percent discount rate, the annualized benefits of the final rule that we were able to quantify, discounted 20 years

into the future, would be $21.0 million. For a discount rate of 7 percent, the annualized quantifiable benefits over 20 years would be $21.0 million.

We incorporated uncertainty into the analysis in our base estimates as presented in the estimated ranges throughout this document. Our estimates rely on a few important additional assumptions:

- The number of import lines will on average grow at the average rate of 3.3 percent per year.[42]
- The number of import lines related to hearings on refusal of admission or administrative destruction for which FDA would provide electronic notice would not change in the future.

We now present a sensitivity analysis that shows how our estimates of costs and benefits of this regulation change if we use different assumptions. We substitute the following assumptions for those used previously:

- The number of import lines will increase at the average rate of 10 percent per year.
- The number of import lines will not grow or decline.
- The number of import lines will decline at the average rate of 5 percent per year.
- The number of import lines will increase at the average rate of 5 percent per year.
- The number of import lines related to hearings on refusal of admission or administrative destruction for which FDA would provide electronic notice would increase between 0 and 10 percent in the future.

[42] We did not use a fixed growth rate of 10 percent because – although it has been the case over the past 5 years, continued growth at that rate is implausible. The future growth rate of import lines is not known, so the Monte Carlo simulation is appropriate to set the range. We estimate the growth rate of 3.3 percent per year as a mean of the Pert distribution with the following parameters: minimum growth rate of 0 percent per year, most likely growth rate of 2.45 percent per year, and maximum growth rate of 10 percent per year.

- The number of import lines related to hearings of refusal of admission or administrative destruction for which FDA would provide electronic notice would decrease between 0 and 10 percent in the future.

Table 14 of this document shows the results of the sensitivity analysis. The discount rate for calculating present value is 3 percent for all sensitivity estimates. Table 14 shows that total costs are most sensitive to the assumption of annual rate of change in the number of import lines; the total benefits are also sensitive to the number of import lines that would require electronic notification of owners and consignees by FDA.

Table 14. Sensitivity Analysis for Assumptions Made for Final Rule (in $millions)

Test	Annualized Cost or Benefit Under Base Assumption	Annualized Cost or Benefit Under Test Assumption	Change in Annualized Cost or Benefit
The number of import lines will increase at the average rate of 10 percent per year (Costs)	$46.7	$90.5	$43.8
The number of import lines will not grow or decline (Costs)	$46.7	$34.9	-$11.8
The number of import lines will decline at the average rate of 5 percent per year (Costs)	$46.7	$23.7	-$23.0
The number of import lines will increase at the average rate of 5 percent per year (Costs)	$46.7	$54.7	$8.0
Increase in the number of import lines that would require electronic notification by FDA (Benefits)	$21.0	$33.1	$12.1
Decrease in the number of import lines that would require electronic notification by FDA (Benefits)	$21.0	$14.2	-$6.8

III. REGULATORY FLEXIBILITY ANALYSIS

A. Introduction

FDA has examined the economic implications of this final 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. The analysis below, together with other relevant sections of this document, serves as the Agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act. We do not believe this final rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain.

B. Estimating the Number of Covered Small Businesses Affected

FDA, for purposes of this rule-making, has defined that a filer is a small business if it employs fewer than 100 employees. This definition is consistent with the definition provided by the SBA's Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS) [2]. We use NAICS code 425120 'Wholesale Trade Agents and Brokers' that defines small businesses as businesses with fewer than 100 employees for this NAICS code. Based on the SBA data [3] we estimate that approximately 99 percent of all wholesale trade agents and brokers employ fewer than 100 employees and therefore are small businesses. Using the U.S. Economic Census data [23] that is available by revenue size

categories for various NAICS codes, we also estimate that these small firms are responsible for about 30 percent of total revenues generated by the wholesale trade agents and brokers industry.

As stated elsewhere in this RIA, in the absence of data about the size or annual sales of importers, we borrow from the economic analysis of the Food Safety Modernization Act Foreign Supplier Verification Program (FSMA FSVP) rule in assuming that importers are equivalent in their characteristics to importers described in the FSMA FSVP rule and that approximately 97 percent of importers are small businesses [4]. Based on these assumptions, we estimate that 40,452 out of 41,703 importers are small businesses.

FDA does not have detailed information on the approximately 3,667 persons (e.g. importers, customs brokers, and other firms that may be filing entries into ACE) that will be responsible for submitting the data elements required by this final rule into ACE. Many of these filers may have fewer than 100 employees, thus making them small businesses as defined by the Small Business Administration [2]. Using the industry general statistics described in the previous paragraph, we estimate that about 3,630 filers (99 percent of all 3,667 filers) are small businesses. We also estimate that these small businesses annually submit entry declarations for about 30 percent of import lines that would be covered by the final rule, or for about 7 million import lines. Based on SBA data [23], businesses in the wholesale trade industry[43] with fewer than 100 employees have average annual sales of $5.5 million; and businesses with fewer than 20 employees have annual sales of $3 million. Therefore, even though the exact impacts on small businesses are uncertain, we estimate that net impact to small businesses covered by this final rule would be minimal compared to their annual sales.

[43] NAICS code 42 - Wholesale Trade.

C. Cost per Entity

Small businesses will be affected by this final rule in the same way as non-small businesses. Because the burden of switching from ACS to ACE is already covered by CBP's regulations, for those small business filers that chose to continue electronically filing import entries and therefore must use ACE, 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.

FDA does not have enough information about the 3,667 ACE filers to perform a detailed analysis of the costs per small business by industry sectors. As estimated above, the per-importer annualized cost is $1,119 with a 3 percent discount rate and $1,080 with a 7 percent discount rate. These small businesses would bear the costs of this final rule, but also enjoy most of the benefits. The per-importer annualized benefits that we were able to quantify are $504 with a 3 percent discount rate, and $504 with a 7 percent discount rate. Benefits that we were not able to quantify at this time arise from improved prevention of risks to public health from non-compliant imports and increased efficiency and streamlining of the overall import process of FDA-regulated commodities; these benefits are presumed to be positive.

IV. CHANGES MADE BETWEEN PRIA AND RIA

In conducting this RIA of the final rule we updated most inputs to the most recent 2015 data using the same sources that we used for the PRIA of the proposed rule (e.g., wage rates, growth rates, etc.). In addition, the number of data elements that would be mandated under the final rule has decreased compared to the number of data elements in the proposed rule. Food

imports other than LACF, ACF, and food contact substances will not be covered by this final rule.

These changes to the final rule resulted in many corresponding changes in the RIA. For example, the number of impacted import lines, importers, filers and unique product-manufacturer combinations has changed from the PRIA to RIA. Annualized over a 20-year horizon at 3 percent discount rate, the costs from the proposed to final rule have decreased by $69 million (range from $25 million to $124 million) because of fewer data elements are required under the final rule; these costs have decreased by $66 million (range from $24 million to $119 million) at a 7 percent discount rate. Quantified benefits have also changed from the proposed to final rule because we were able to more precisely estimate FDA labor cost savings in estimating benefits from electronically issuing notices related to hearings on refusal of admission or administrative destruction. In quantifying other benefits such as potential cost savings to industry from a more streamlined processing of import entry declarations by FDA we encountered greater uncertainty. This is because ACE pilot data does not well-represent the typical time savings that FDA anticipates industry would enjoy after the initial ACE adjustment process. In the RIA for the final rule we qualitatively described and reported these cost savings under benefits that were not quantified.

V. REFERENCES

The following references have been placed on display in the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified all the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.

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