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 Proposed Rule

Initial Regulatory Flexibility Analysis

Unfunded Mandates Reform Act Analysis

FDA–2016–N–1487

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SUMMARY: Pursuant to Executive Order 13569, the U.S. Customs and Border Protection (CBP) agency established a new Automated Commercial Environment (ACE) system that will replace the existing Automated Commercial System (ACS) currently used by CBP for import admissibility decisions. The Food and Drug Administration (FDA, Agency, or we) is issuing a proposed rule to establish requirements for the entry of certain FDA-regulated products in ACE in order for an import filing to be accepted by CBP and to help FDA in determining admissibility. This proposed 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 admissibility determination 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 products that are not in compliance with the FD&C Act or the 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 proposes technical revisions to certain sections of 21 Code of Federal Regulations (CFR) 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) clarifying that importers of record of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Services Act and 21 CFR part 1271, unless exempted, would be required to submit the applicable data elements included in the proposed 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 proposed rule [FDA-2016-N-1487].

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Summary of Preliminary Economic Analysis of Impacts of the Proposed Rule

As a result of CBP's switch from ACS to ACE, FDA is proposing a rule that would require certain data elements material to imports admissibility determination into the U.S. be submitted to the FDA via ACE as a part of import entry request. The proposed regulation would help streamline FDA's existing admissibility procedures for FDA-regulated commodities imported or offered for import into the United States. For import entry requests submitted electronically, FDA would require that certain key data be submitted as a part of the import entry request filing in the new ACE system. This rule proposes to make the submission of these data elements mandatory in ACE for each import entry line for the FDA-regulated commodities specified in the proposed rule for which entry requests are submitted electronically. The proposed regulation also provides further clarifications to the import process by revising sections of 21 CFR relating to the definition of owner or consignee; the notice of sampling; the notices of FDA actions related to FDA-regulated products imported or offered for import into the U.S., such as notices of hearing on refusal of admission or destruction, and by allowing for electronic notification by FDA; and clarifying that importers of record of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Services Act and 21 CFR part 1271, unless exempted, would be required to submit the applicable data elements included in the proposed rule in ACE.

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

The costs 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 proposed rule. The main impact of this rule on these firms would be that as a part of import entry request, 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 practice, and on whether filers are already submitting some of this information into ACS.[1]

The estimated costs of this proposed rule – and the cost savings – stem from the mandatory information that would be submitted and collected under the ACE system. In the baseline scenario for our estimates of these costs, we treated ACS as the shell for the submission of the information but assumed that without the proposed FDA regulation, the information would be collected by ACE only if voluntarily provided by filers like under the current ACS system (scenario 1, Table 1). An alternative baseline is CBP implementation of ACE with the data elements for the entry of FDA-regulated products (scenario 2, Table 1). Under this scenario, the benefits, costs, and costs savings estimated for the proposed rule would be the same but would be attributed to ACE's full implementation. The incremental costs and costs savings of this proposed rule, should it become final, would be zero under this baseline (scenario 2, Table 1). This scenario now appears likely, with the transition to ACE is well under way and the ACE system scheduled to become the only CBP-authorized electronic data interchange system for the electronic filing of entries containing an FDA-regulated product this year.

[1] In this PRIA, we do not include benefits and costs from data elements that are already being routinely submitted by some filers into ACS/ACE.

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

Discount Rate	Total Annualized Costs	Total Benefits	
		Cost Savings	Other Benefits (Not Quantified)
SCENARIO 1 – the benefits, the costs and costs savings are attributed to FDA regulation			
3 percent	$116 million (range $53 million to $193 million)	$37 million (range $3 to $89 million)	More efficient use of FDA's internal resources; potentially fewer import recalls; reduced misbranding; reduction of counterfeit imports on the U.S. market; increased efficiency of the overall import process due to fewer errors because of a better defined *the owner or consignee* term, the clarifications related to notice of sampling, and allowing for electronic notice of hearing on refusal of admission and notice of destruction of drugs.
7 percent	$111 million (range $51 million to $186 million)	$36 million (range $3 million to $88 million)	More efficient use of FDA's internal resources; potentially fewer import recalls; reduced misbranding; reduction of counterfeit imports on the U.S. market; increased efficiency of the overall import process due to fewer errors because of a better defined *the owner or consignee* term, the clarifications related to notice of sampling, and allowing for electronic notice of hearing on refusal of admission and notice of destruction of drugs.
SCENARIO 2 - the benefits, costs and costs savings estimated under SCENARIO 1 would still be incurred, but would be attributed to the implementation of ACE			
3 percent	$0	$0	$0
7 percent	$0	$0	$0

Table 1 shows that under scenario 2, the incremental effects of the proposed rule would be zero; the benefits, costs, and costs savings would still be incurred but would be attributed to ACE implementation by CBP. Under the alternative scenario 1 the costs and costs savings and the benefits would be incurred and attributed to this rulemaking by FDA.

What follows in this PRIA is the analysis for scenario 1. We estimate that under this scenario 1 in the first year the costs of this proposed regulation would range from $44 million to

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

$160 million, with the best estimate of $96 million.[3] In the steady state, the best estimate costs would range from $88 million to $159 million per year. Table 1 shows the total costs, cost savings, and other benefits of this proposed 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 $53 million and $193 million per year with the best estimate of $116 million per year with a 3 percent discount rate; these costs are between $51 million and $186 million per year with the best estimate of $111 million per year with a 7 percent discount rate (Table 1). The present discounted value of total costs of this proposed rule is $1,721 million at a 3 percent discount rate and $1,180 million at 7 percent discount rate. The per-importer annualized cost is $1,951 with a 3 percent discount rate and $1,878 with a 7 percent discount rate.

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 $3 million to $89 million, with the best estimate of $37 million per year with a 3 percent discount rate; these partially quantifiable benefits are estimated to range from $3 million to $88 million, with the best estimate of $36 million per year with a 7 percent discount rate (Table 1). The per-importer annualized benefits that we were able to quantify are $620 with a 3 percent discount rate and $609 with a 7 percent discount rate. Some of these cost savings to both the industry and FDA that we are able to only partially quantify would arise from the reduced time of import entry request processing and fewer and shorter product holds as a result of increased efficiency of FDA's imports admissibility process. Benefits, in terms of cost savings, to both FDA and the industry that we are able to quantify would also arise from FDA

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

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.

Other potential benefits of this proposed rule that we are unable to quantify at this time 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 the Agency would provide more clarity to the industry about the overall process of importing FDA-regulated products.

I. INTRODUCTION

FDA has examined the impacts of the proposed 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 Agencies to assess all costs and benefits (both quantitative and qualitative) 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 proposed rule. We believe that this proposed rule may be a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies 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 proposed rule into ACE and updating certain

sections of 21 CFR the FDA intends to streamline import entry requests and reduce ambiguity about the import process. Small businesses will be affected by this proposed 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 propose that providing several additional data elements to FDA via ACE in exchange for a more streamlined process for potentially receiving an import admissibility decision faster would not cause a significant impact. These small businesses would bear the costs of this rule, but would also enjoy most of the benefits. We therefore do not believe this proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain so we are explicitly seeking comment on the impacts.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Need for This Regulation

This proposed rule seeks to improve FDA's ability to ensure public health by specifying certain required data elements be submitted as a part of import entry via ACE. This proposed regulation would also provide clarification to the import process by revising certain sections of

the 21 CFR language related to import process and electronic notification about hearings on refusal of admission or administrative destruction.

Globalization of world markets has increased imports of certain FDA-regulated products into the U.S. In the drugs and medical devices markets, for example, development of complex and fragmented global supply chains that transformed these industries allowed for increased trade 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 for FDA of ensuring protection of public health in regards to FDA-regulated imports. Even though importers and other businesses that may be impacted by this proposed 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 the global distribution system process as a whole as may relate to public health and safety.

Global distribution system is becoming more and more complex and, although private incentives lead to private efforts to protect product safety and quality at the firm level because the consequences would be costly for that firm, there are external effects associated with privately produced information and protection. Private incentives fail 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, the external

effects associated with more complete information is needed where it can be centrally used if needed will not be realized if private incentives alone guide collection and provision of information on FDA regulated imports.

No individual firm or organization has sufficient financial incentives to establish a central information system relating to import safety for the entire U.S. economy similar to ACE system. All participants of the import industry, however, benefit from such a system because it would facilitate uncovering and solving problems associated with products being imported or offered for import into the U.S., but the private costs to create the 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 cost.

Under the current ACS system, which is a centralized non-private information system, the amount of information provided by filers into ACS is sub-optimal. Filers spending additional time and resources to provide more information to FDA (via ACS) than is currently required for import entry decision may result in faster 'may proceed' decisions by FDA, but for fewer import entries than potentially can happen under ACE. This is in part because of the way ACS is designed and operates and in part because to make risk-based evaluations and admissibility decisions potentially faster, FDA needs additional new data elements beyond what is required to be submitted through ACS. As a result of firms not providing certain information to FDA, FDA is unable to operate as efficiently as possible when making risk-based import entry decisions.

More generally, the need for improving the efficiency of the overall import process is emphasized by Executive Order 13569. According to Executive Order 13569, by December 2016 CBP must establish the new ACE system. ACE is the electronic import system that importers of record should use for electronically filing import entry requests; it is designed to simplify and speed up the import process. ACE will replace the ACS that is currently operated by CBP for import processing. Key to ACE is the new way of submitting trade information called International Trade Data System (ITDS). ITDS is the "single-window" capability of ACE that allows businesses to submit all data required by participating federal agencies for import and export cargo into a single portal.[4] ACE/ITDS electronically transmits this trade information to the multiple agencies with border responsibilities, including FDA.

What follows in this PRIA is the analysis for scenario 1 (Table 1).

B. Coverage of the Analysis

In order to assess the total costs and cost savings of this proposed 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 rule, 2014

Entity type	US entity	Foreign entity	Total
Importers (owners and purchasers)	49,786	9,506	59,292
Filers	4,010	0	4,010
Ultimate Consignees	397,038	0	397,038

[4] This proposed rule would only concern import cargo.

Entity type	US entity	Foreign entity	Total
Foreign manufacturers	0	321,028	321,028
Shippers	266,002		266,002

The regulated community for the proposed rule consists of firms that offer FDA-regulated products for import into the U.S. and would file electronic entry requests with CBP via ACE. Based on the FDA internal 2014 data [1], we estimate there are about 59,292 importers (owners and purchasers) of FDA-regulated commodities that would be potentially impacted by this proposed rule (Table 2); about 84 percent of them are U.S. firms. These importers either file these electronic import entry requests and the required supplemental data in ACS themselves or hire a customs broker licensed by CBP.[5] Although other types of entities may be involved in the process of import entry, we assume that the importer would bear the actual burden of this proposed rule even if the importer, for example, hires a customs broker to complete some of the tasks in order to comply with this proposed regulation. We estimate that there are a total of 4,010 entry filers, which includes the 1,364 owners or purchasers of the article who will file their own import entry in ACE (=59,292 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

[5] A filer is an entity that files an import entry request 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 94 and 99 percent with a best estimate of 97.7 percent of importers use brokers to file import entries [1].

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 57,513 out of 59,292 importers are small businesses and that 3,970 out of 4,010 entry filers are small businesses. We request 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 proposed rule-making.

According to CBP, currently 96 percent of import entry requests 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 out of a total of 35.4 million import lines, about 34 million[8] import lines would be covered by the proposed rule because they were submitted electronically. According to FDA internal data [6], in 2014 about 2.87 percent 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 proposed rule if foreign importers are fluent in English and thus do not need more time to complete certain tasks. If importers themselves are

[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 other food and non-food imports covered by this proposed regulation. We also assume that that size distribution among these businesses is similar to the ones covered by the FSMA FSVP rule.

[7] Importers can file entry requests and the supporting documentation with CBP and FDA either electronically or by paper. 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 requests by paper would not be impacted by the proposed rule but remain subject to CBP requirement 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 [9]. We estimate that about 34 million electronically-filed import lines (= 35.4 million lines x 0.96) will be affected by this proposed rule.

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.

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 request. 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 proposed 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 is not a viable option. The current situation, then, cannot be the baseline for this analysis. Under the baseline of no proposed regulation, FDA would continue receiving some voluntary data from the industry, but would still have to link CBP's ACE to FDA's internal decision-making system because CBP will decommission ACS. As such, there

[9] Many of these importers are firms that are required by law or regulation to already 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.

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 requests electronically interact with CBP through the Automated Broker Interface (ABI).[11] The data filed by these filers then gets automatically transmitted from ABI into CBP's ACS system for processing. The ACS 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. It is expected that after all phases of ACE interface release are completed by CBP, CBP would decommission the ACS interface.

CBP currently collects, 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 collects on behalf of FDA collects certain "affirmations of compliance," which vary by type of product. Providing this information often helps expedite the admissibility decision by FDA, resulting in time savings to the importer, their trading partners, and FDA.[12]

[11] CBP reports that current entry submission methods include electronic and non-electronic (paper) formats, although most import entry requests are submitted electronically [5]. Submitters that choose to file manually (non-electronically) using paper format at the port of entry and the nearest FDA office would not be affected by this proposed 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 by FDA to make an import entry decision.

[12] Even if the data is submitted electronically, other factors may influence FDA's decision to take additional review steps to ensure product safety. 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 a manual review. [13] This average is weighted by the number of import lines in each product category.

The 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).

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

Product Category	Annual Number of Import Lines	Import Lines, Percent of Grand Total	Percent of Lines Currently Submitted 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 (except Food Contact Substances and LACF, ACF)	11,768,706	33.2%	na
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 current voluntary data submission practices by industry. It shows that based on 2015 FDA internal data [1], the share of lines submitted without at least some of the voluntary information was as low as 2 percent for medical devices and as high as 91 percent for biologic products (Table 3). At least some voluntary data was provided by filers for nearly 98 percent of all medical device import lines that represented about 71 percent of total FDA-regulated lines covered by this proposed rule [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 This Proposed Rule and the Number of Elements that Would Require Additional Compliance Time, by Product Category

Product Category	general data elements				product-specific data elements				Total
	new	in ACS and will be mandated in ACE	mandated by other FDA rules	that would need compliance time	new	in ACS and will be mandated in ACE	mandated by other FDA rules	that would need compliance time	
Animal Drugs	1	4	0	5	0	3	0	3	8
Biologics	1	4	0	5	1	5	0	6	11
Cosmetics	1	4	0	5	0	0	0	0	5
Human Drugs	1	4	0	5	0	3	0	3	8
Food (excluding LACF/ACF and Food Contact Substances)	1	0	0	1	0	0	0	0	1
Food Contact Substances	1	4	0	5	0	0	0	0	5
LACF, ACF	0	4	0	4	0	3	0	3	7
Medical Devices	1	4	0	5	0	8	0	8	13
Radiation-Emitting Electronic Products	1	4	0	5	0	14	14	0	5
Tobacco	1	4	0	5	2	0	0	2	7
Weighted[13] Average	**1.0**	**2.7**	**0.0**	**3.7**	**0.0**	**4.3**	**0.4**	**3.9**	**7.6**
Weighted Average (after incorporating uncertainty)[14]	**1.0**	**1.3**	**0.0**	**2.3**	**0.0**	**1.4**	**0.4**	**1.0**	**3.3**

[13] This average is weighted by the number of import lines in each product category.

[14] Some filers routinely provide some of the data elements in ACS and not all product-specific data elements apply to each commodity in that product category, but we lack the exact data. We use a uniform distribution with a minimum of zero percent and a maximum of 100 percent to account for these uncertainties.

Table 4 shows that depending on product type, this proposed regulation newly-mandates the submission of between 1 and 13 data elements per import line; this is in addition to data elements that are now routinely submitted in ACS. Not every element is mandated for each product in the same category and, as previously stated, some filers are already voluntarily submitting some of these data elements. For example, for medical devices between 2 and 3 data elements per import line are currently being voluntarily submitted to FDA via ACS [6]. We estimate that because some filers are already submitting some of these data elements voluntarily firms would need to prepare and submit into ACE information on 1 to 8 mandatory data elements per import line, with the best average estimate of 3 data elements (Table 4).

Under the current baseline import process, after FDA's OASIS receives the import entry information from CBP's ACS, FDA's risk-based electronic evaluation tool "Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting" commonly known as PREDICT quickly screens all 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 ACS 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 is subject to refusal of admission.

Without the proposed rule and once CBP decommissions ACS, FDA would lose the OASIS-ACS link and, hence, access to all of the data elements currently voluntarily submitted by importers into ACS. FDA would have to make arrangements for either linking ACE to

FDA's OASIS to continue systematically receiving this information or request that firms provide this information directly to FDA. The latter approach is a more costly approach because it would require multiple additional FDA staff members and resources.

In addition, without changes to data currently submitted in ACS, 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, continue to include the cost of linking 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 submitting the voluntary data to FDA. Such approaches would be inconsistent with Executive Order 13569 that directs to "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 proposed rule will also continue increasing in the future.

[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.

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 34 million electronically-filed import lines will be affected by this proposed 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 proposed rule will continue to grow at a rate of between 0 and 10 percent per year, with the most likely rate of 2.5 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 Proposed Regulation[17]

Year	The Number of Import Lines Covered by This Proposed Regulation	The Number of New Unique Product-Manufacturer Import Lines Covered by This Proposed Regulation
1	33,988,154	975,460
2	35,121,092	1,007,975
3	36,291,796	1,041,575
4	37,501,522	1,076,294
5	38,751,573	1,112,170
6	40,043,292	1,149,242
7	41,378,068	1,187,551
8	42,757,337	1,227,136
9	44,182,582	1,268,040
10	45,655,335	1,310,308
11	47,177,179	1,353,985
12	48,749,752	1,399,118
13	50,374,743	1,445,755
14	52,053,901	1,493,947
15	53,789,032	1,543,745
16	55,581,999	1,595,203
17	57,434,733	1,648,377
18	59,349,224	1,703,323

[16] We estimate that growth rate of about 2.5 is consistent with the average Gross Domestic Product (GDP) growth rate of the U.S. economy for the 20-year period between 1994 and 2014 [24]. 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 2.5 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.

Year	The Number of Import Lines Covered by This Proposed Regulation	The Number of New Unique Product-Manufacturer Import Lines Covered by This Proposed Regulation
19	61,327,531	1,760,100
20	63,371,782	1,818,770

C. Option 1 - The Proposed Rule

Costs and Benefits of the Proposed Rule

Under the proposed rule, for each article that is subject to FDA regulation and covered by the proposed rule, importers must submit certain new 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 proposed rule, importers of FDA-regulated commodities would need to complete certain start-up activities in the first year and maintain certain activities in subsequent years under the steady state years. We estimate that the costs to both domestic and foreign entities of complying with the proposed rule is based largely on the amount of additional time it would 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 request using software that is connected to ACE.[19] If importers find that it is more cost effective to delegate some of these

[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 request 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 proposed 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.

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 doesn't matter who performs each of these tasks, but the person who is liable for complying with this regulation is the importer of record.

Estimates of costs to industry from the proposed 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 and best professional judgment [1], [6], [10], [11], [8]. Table 6 summarizes annual costs to the industry. We estimate that in the first year the total cost of this proposed rule is between $44 million and $160 million per year[21], with the best estimate of $96.0 million; in the steady state, this best estimate cost would range between $88.3 million and $159.2 million depending on the year (Table 6). Annualized over 20 years, these costs are $115.7 million per year with a 3 percent discount rate and $111.3 million per year with a 7 percent discount rate (Table 6). FDA acknowledges the uncertainty of these calculations and requests comments regarding these estimates.

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

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

Year	Undiscounted Regulatory Costs				Present Value with Discount Rate[22]	
	Costs of reading the rule	Costs of preparing data	Costs of quality check and submission into ACE	Total Cost by Year	3%	7%
1	$0.2	$2.2	$93.6	$96.0	$93.3	$89.8
2	$0.0	$2.3	$86.0	$88.3	$83.2	$77.1
3	$0.0	$2.4	$88.8	$91.2	$83.5	$74.4
4	$0.0	$2.5	$91.8	$94.2	$83.7	$71.9
5	$0.0	$2.5	$94.9	$97.4	$84.0	$69.4
6	$0.0	$2.6	$98.0	$100.6	$84.3	$67.1
7	$0.0	$2.7	$101.3	$104.0	$84.6	$64.8
8	$0.0	$2.8	$104.7	$107.4	$84.8	$62.5
9	$0.0	$2.9	$108.2	$111.0	$85.1	$60.4
10	$0.0	$3.0	$111.8	$114.7	$85.4	$58.3
11	$0.0	$3.1	$115.5	$118.6	$85.7	$56.3
12	$0.0	$3.2	$119.3	$122.5	$85.9	$54.4
13	$0.0	$3.3	$123.3	$126.6	$86.2	$52.5
14	$0.0	$3.4	$127.4	$130.8	$86.5	$50.7
15	$0.0	$3.5	$131.7	$135.2	$86.8	$49.0
16	$0.0	$3.6	$136.0	$139.7	$87.0	$47.3
17	$0.0	$3.8	$140.6	$144.3	$87.3	$45.7

[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).

Year	Undiscounted Regulatory Costs				Present Value with Discount Rate[22]	
	Costs of reading the rule	Costs of preparing data	Costs of quality check and submission into ACE	Total Cost by Year	3%	7%
18	$0.0	$3.9	$145.3	$149.1	$87.6	$44.1
19	$0.0	$4.0	$150.1	$154.1	$87.9	$42.6
20	$0.0	$4.1	$155.1	$159.2	$88.2	$41.2
Total Years 1 to 20				$2,385.1	$1,720.8	$1,179.6
Annualized Total Over 20 Years					$115.7	$111.3

The proposed rule would also update FDA's current regulations on imports by proposing an option of electronically notifying 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 destruction. Thereby, this proposed regulation would enhance FDA's capabilities of faster responding to importers regarding imports safety matters and allow FDA to better use its limited resources.

We estimate that the potential benefits to both FDA and the industry would occur because of the reduced time of entry request processing and fewer and shorter product holds as a result of increased efficiency of the FDA's entry decision process. Because of the limited industry data and uncertainty we are able to only partially quantify these benefits; they are estimated to range $0.4 million to $64 million per year[23], with the best estimate of $12.0 million to $22.3 million per year (Table 7). Benefits to the general public that we are unable to quantify at this time would result from FDA-regulated imports reaching the U.S. consumers faster and from fewer

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

non-compliant imports reaching the U.S. consumers, which would improve the overall safety of FDA-regulated imports on the U.S. market and thereby would 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 would also arise from increased efficiency of the import process. This is because by revising certain sections of the 21 CFR FDA would provide more clarity to the industry about the overall import process of FDA-regulated products. In addition, benefits that would range between $2 million and $43 million per year[24], with the best estimate of $20.7 million per year in the form of cost saving to both the industry and FDA would arise because with this proposed rule FDA would simplify 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 $36.8 million per year with a 3 percent discount rate and $36.1 million per year with a 7 percent discount rate (Table 7). FDA acknowledges the uncertainty of these calculations and requests comments regarding these estimates.

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

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

Year	Undiscounted Regulatory Benefits (Quantifiable Only)				Present Value with Discount Rate[25]	
	Benefit to the industry from receiving 'may proceed' faster	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	$12.0	$20.4	$0.3	$32.6	$31.7	$30.5
2	$12.4	$20.4	$0.3	$33.0	$31.1	$28.8
3	$12.8	$20.4	$0.3	$33.4	$30.6	$27.3
4	$13.2	$20.4	$0.3	$33.9	$30.1	$25.8
5	$13.7	$20.4	$0.3	$34.3	$29.6	$24.4
6	$14.1	$20.4	$0.3	$34.7	$29.1	$23.2
7	$14.6	$20.4	$0.3	$35.2	$28.6	$21.9
8	$15.1	$20.4	$0.3	$35.7	$28.2	$20.8
9	$15.6	$20.4	$0.3	$36.2	$27.7	$19.7
10	$16.1	$20.4	$0.3	$36.7	$27.3	$18.7
11	$16.6	$20.4	$0.3	$37.3	$26.9	$17.7
12	$17.2	$20.4	$0.3	$37.8	$26.5	$16.8
13	$17.7	$20.4	$0.3	$38.4	$26.1	$15.9
14	$18.3	$20.4	$0.3	$39.0	$25.8	$15.1
15	$18.9	$20.4	$0.3	$39.6	$25.4	$14.3
16	$19.6	$20.4	$0.3	$40.2	$25.1	$13.6
17	$20.2	$20.4	$0.3	$40.9	$24.7	$12.9
18	$20.9	$20.4	$0.3	$41.5	$24.4	$12.3
19	$21.6	$20.4	$0.3	$42.2	$24.1	$11.7
20	$22.3	$20.4	$0.3	$43.0	$23.8	$11.1
Total Years 1 to 20				$745.6	$546.8	$382.6
Annualized Total Over 20 Years (Quantifiable Only)					$36.8	$36.1

Costs of the Proposed Regulation

[25] 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).

Rule Familiarization (one-time cost)

The costs of becoming aware of the requirements of the rule arise because importers and filers must familiarize themselves with the proposed rule. This administrative cost may include some or all of the following: reading the rule[26], understanding the reporting requirements, consulting with specialists if necessary, familiarizing themselves with the revisions of privately-developed computer software that are related to this proposed rule, determining how to best meet these 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 proposed rule are required for submission into ACE as a part of an import entry request for every FDA-regulated product covered by this proposed 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 would be impacted by this proposed 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 requests for FDA-regulated imports are filed by custom brokers rather than importers. Based on FDA's internal data [1], we estimate that in 2014 about 97.7 percent of importers used customs brokers to file import entry requests. This suggests that the majority of importers would rely on the custom brokers to read and understand this proposed regulation and tell them what is needed to comply with this proposed 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

[26] We have found [10] that most filers may not take a long time to read this proposed 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. 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 request. Furthermore, the proposed 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. Furthermore, most of the data elements required by the proposed rule are currently collected in ACS, so filers should be familiar with them.

entrants into the system would still primarily rely on the already knowledgeable customs brokers to communicate to them the requirements of this 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 into this analysis.

Administrative costs of familiarization with the rule are summarized in Table 8. We estimate that, for each of the 4,010 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 proposed rule. The base wage rate of $56.35 is taken from the May 2014 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 $112.70. We estimate that to become familiar with the requirement of this proposed regulation, a total of 4,010 filers, including 1,364 importers (= 59,292 importers x (100-97.7) percent), would in total spend between 634 and 3,376 hours, with the best estimate of 2,005 hours, at a total cost of between $0.07 million and $0.4 million, with the best estimate of $0.2 million (Table 8).[27] This results in an average burden of between 0.16 hours and 0.84 hours per filer at a cost of between $18 and $95, with the best estimate of $56 per filer (Table 8).

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

	Number of Responders	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm
First Year	4,010	One time	0.5	2,005	$112.70	$0.2	$56

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

Preparing the Required Information

In the first year, for any import lines that represent unique product-manufacturer combinations, an importer would need to establish the internal data sources and documents that contain information mandated by this proposed rule and to prepare this information for submission into ACE or for his broker.[28] According to the information by the FDA's Office of Regulatory Affairs [6], in 2014 there were about 975,460 import lines that represented unique product-manufacturer combinations, or about 2.87 percent of all import lines that would have been covered by this proposed rule if it was implemented before 2014. This share of 2.87 percent represents the share of new unique import lines for which we estimate each year a filer would need to prepare information required by this proposed rule for submission into ACE.

Every year the additional time spent preparing all of the information mandated by the proposed rule would vary depending on data element, product type, importers' and brokers' internal 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 8 additional minutes[29] with the best estimate of 3 minutes (range of 0.167 to 0.0133 hours with the mean estimate of 0.067 hours)[30]

[28] 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.
[29] These lower and upper bounds were estimated using the weighted average corrected for uncertainty 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.
[30] This is an estimate of one minute per data element.

per unique product-manufacturer import line to locate and gather all the information[31] required by this proposed rule (Table 9).

For the purpose of this analysis, we estimate that for each unique product-manufacturer import line covered by this proposed 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 97.1 percent of all import lines covered by this proposed rule); this duplicative information will be already in the existing importer's or broker's databases and readily available to them. FDA requests comments regarding the accuracy of this assumption that all of the required data are readily available to importers for the majority of import lines that are not unique product-manufacturer combinations.

Table 9 shows that we estimate that in the first year the average frequency of filing unique product-manufacturer import entry requests of FDA-regulated products covered by this proposed rule will be about 16 import lines per importer (= (34 million electronically-filed import lines x 2.87 percent) / 59,292 importers). The base wage rate of $17.08 per hour are taken from the May 2014 BLS Occupational Employment Statistics for administrative workers [13] and increased by 100 percent to $34.16 to include overhead costs and benefits. We estimate

[31] 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 requests for them.

that the total cost of preparing information mandated by this proposed rule for ACE entry for new unique product-manufacturer combination import lines would range between $1.0 million to $3.7 million[32], with the best estimate of about $2.2 million in the first year and between $2.3 million and $4.1 million per year in years two through twenty (Table 9).

Table 9. Cost of Preparing Information for Import Entry Filing (Unique Product-Manufacturer Import Lines Only)[33]

Year	Number of Respondents	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm
1	59,292	16	0.067	65,031	$34.16	$2.2	$37
2	59,292	17	0.067	67,198	$34.16	$2.3	$39
3	59,292	18	0.067	69,438	$34.16	$2.4	$40
4	59,292	18	0.067	71,753	$34.16	$2.5	$41
5	59,292	19	0.067	74,145	$34.16	$2.5	$43
6	59,292	19	0.067	76,616	$34.16	$2.6	$44
7	59,292	20	0.067	79,170	$34.16	$2.7	$46
8	59,292	21	0.067	81,809	$34.16	$2.8	$47
9	59,292	21	0.067	84,536	$34.16	$2.9	$49
10	59,292	22	0.067	87,354	$34.16	$3.0	$50
11	59,292	23	0.067	90,266	$34.16	$3.1	$52
12	59,292	24	0.067	93,275	$34.16	$3.2	$54
13	59,292	24	0.067	96,384	$34.16	$3.3	$56
14	59,292	25	0.067	99,596	$34.16	$3.4	$57
15	59,292	26	0.067	102,916	$34.16	$3.5	$59
16	59,292	27	0.067	106,347	$34.16	$3.6	$61
17	59,292	28	0.067	109,892	$34.16	$3.8	$63
18	59,292	29	0.067	113,555	$34.16	$3.9	$65
19	59,292	30	0.067	117,340	$34.16	$4.0	$68
20	59,292	31	0.067	121,251	$34.16	$4.1	$70
Total				**1,807,872**		**$61.8**	

[32] We generated upper and lower bounds using Monte Carlo simulations.
[33] All cost estimates in this table are rounded to the nearest dollar.

Quality check of data and ACE submission

The proposed rule would make the submission of certain data elements mandatory. To ensure the accuracy of data submitted for the information submitted in ACE for all import lines of FDA-regulated products covered by this proposed rule, we estimate that either the importer or the filers would perform an additional step prior to or at a time of submitting these data elements into ACE – data quality checks. This step would apply to all data elements listed in the proposed rule regardless of whether an importer was previously submitting some of these data elements into ACS. Instead of relying on managers all the time, some filers may rely on automated messages from CBP to identify missing or incorrect data in case if the entry is rejected. 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 proposed 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 proposed 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 proposed rule.

Based on FDA internal data [1], we estimate that in the first year, the frequency of import entry filings covered by this proposed regulation will be 8,476 import line entry requests per filer (= (34 million import lines) / 4,010 filers), or about 163 import lines per week (Table 10). In the subsequent years, the annual frequency would range between 8,758 and 15,803 import entry request 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[34] 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 $73.43 (= (112.7 + 34.16) / 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 4 minutes in total, with the best estimate of 1.5 minutes (and a mean estimate of about 2 minutes or 0.033 hours hours) in total per import line to conduct quality check of the data elements mandated by this proposed 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 way of filing newly-mandated by FDA data elements will be involved for some filers and that it would take filers between 0 and 25 percent more time to complete this task in the first year. In total, we estimate that in the first year it would cost between $43.0 million and $156.1 million[35] with the best estimate of $93.6 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 $39.5 million to $258.7 million[36], with the best estimate of between $86.0 million and $155.1 million.

Table 10. Cost of Performing Quality Data Checks and Submitting it into ACE

Year	Number of Respondents	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm, in $millions
1	4,010	8,476	0.033	1,274,556	$73.43	$93.6	$0.023
2	4,010	8,758	0.033	1,170,703	$73.43	$86.0	$0.021
3	4,010	9,050	0.033	1,209,727	$73.43	$88.8	$0.022

[34] We take into consideration that some software stores previous information and can automatically populate some information from previous similar import entry filings [10].
[35] We generated upper and lower bounds using Monte Carlo simulations.
[36] We generated upper and lower bounds using Monte Carlo simulations.

Year	Number of Respondents	Annual Frequency	Hours per Respondent	Total Hours	Wage	Total Cost, in $millions	Cost per firm, in $millions
4	4,010	9,352	0.033	1,250,051	$73.43	$91.8	$0.023
5	4,010	9,664	0.033	1,291,719	$73.43	$94.9	$0.024
6	4,010	9,986	0.033	1,334,776	$73.43	$98.0	$0.024
7	4,010	10,319	0.033	1,379,269	$73.43	$101.3	$0.025
8	4,010	10,663	0.033	1,425,245	$73.43	$104.7	$0.026
9	4,010	11,018	0.033	1,472,753	$73.43	$108.2	$0.027
10	4,010	11,385	0.033	1,521,844	$73.43	$111.8	$0.028
11	4,010	11,765	0.033	1,572,573	$73.43	$115.5	$0.029
12	4,010	12,157	0.033	1,624,992	$73.43	$119.3	$0.030
13	4,010	12,562	0.033	1,679,158	$73.43	$123.3	$0.031
14	4,010	12,981	0.033	1,735,130	$73.43	$127.4	$0.032
15	4,010	13,414	0.033	1,792,968	$73.43	$131.7	$0.033
16	4,010	13,861	0.033	1,852,733	$73.43	$136.0	$0.034
17	4,010	14,323	0.033	1,914,491	$73.43	$140.6	$0.035
18	4,010	14,800	0.033	1,978,307	$73.43	$145.3	$0.036
19	4,010	15,294	0.033	2,044,251	$73.43	$150.1	$0.037
20	4,010	15,803	0.033	2,112,393	$73.43	$155.1	$0.039
Total				**31,637,638**		**$2,323.2**	

Benefits of the Proposed Regulation

The benefits that would result from this proposed rule can be divided into the following categories: (a) cost savings to industry as a result of FDA's improved ability to process entries in a more timely and effective manner because of new ACE data; (b) cost savings to FDA as a result of more efficient processing of entries resulting from the availability of enhanced data set; (c) benefits to the general public from a more efficient import process and safer imports available on the U.S. market because of new ACE data; (d) 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 Proposed Rule

Benefit	Who benefits	Benefits	Description
Cost savings to industry from FDA's improved ability to better streamline the entry admissibility process due to the availability of the new ACE data	Industry	Partially quantifiable benefits of $12.0 million to $22.3 million, depending on the year (range $0.4 million to $64.5 million)	Improved predictability of the import process; potentially fewer import holds; potentially shorter import holds 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 and safer imports	The general public, industry	Not quantified	Potentially fewer import recalls, reduced misbranding, reduction of counterfeit products on the U.S. market
Cost savings from a better informed import process	Industry	Not quantified	Fewer errors because of a better defined the *owner or consignee* term and the clarifications related to notice of sampling, notice on refusal, notice of destruction of drugs, and HCT/P products
Cost savings to FDA from electronically providing notices of hearing on refusal of admission or destruction	FDA, industry	Fully quantifiable, $20.6 million (range $2.0 million to $42.7 million)	Warehousing and storage cost savings for importers; FDA labor cost savings.

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

We expect that the benefits from the proposed rule in a form of cost savings to both FDA and industry would include time savings. These 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 requests:

- Potential reduced time for processing import entry requests by FDA;
- Potentially fewer import holds;
- Potentially shorter import holds 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 risk-based approach to admissibility decisions and more effectively utilize its limited human capital resources. After an import entry filer submits into ACS or ACE (and after the implementation of ACE all filers would submit into ACE) an import entry request and all the required information is transmitted to FDA, FDA processes the entry including filtering the data through PREDICT and reviews the entry either in an automated fashion or manually. Next, the disposition of the entry is sent back through ACS or ACE to filers. This message indicates FDA's initial decision on whether: (a) the product may proceed into the U.S., (b) additional information is required, (c) an examination is required, or (d) the shipment is subject to refusal of admission. According to FDA's internal data [1], in 2014 an automatic 'may proceed' decision was issued in 0-53 percent of cases depending on the product type. More information from importers and more accurate data would allow FDA to potentially increase the

average number of automatic 'may proceed' outcomes. After the implementation of the ACE system, by accurately providing FDA with the information on ACE data elements required by this proposed rule, most importers may potentially be able to increase the probability of faster receiving 'may proceed' from FDA, potentially reduce the probability of having to submit additional information to FDA after the initial submission, potentially reduce the probability of a product hold for their imports, or potentially reduce the length of a detention period if it occurs.

Currently, for importers and other industry participants that don't get automatic 'may proceed' outcomes for a product, the import process often takes relatively longer in part because of the relatively longer wait to clear import entries. Using FDA's Office of Regulatory Affairs Reporting, Analysis and Decision Support System (ORADSS), FDA internal data query [1], we estimate that in 2015 on average it took between 12 and 40 hours for a manual 'may proceed' decision[37] for FDA-regulated imports that would be covered by this proposed rule, with the best estimate of 21 hours[38]. By complying with this proposed rule importers and filers may be able to potentially eliminate this waiting period, which would result in cost savings. These cost savings are estimated as 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 proposed rule getting an automatic 'may proceed' decision would occur for most entries or only for some entries.[39] By multiplying the number of hours potentially saved by importers by the annual rate of return on capital[40] and by the approximate annual volume of imports that would be covered by this proposed rule (which we estimate as about $261.4 billion in the first year [11]), we estimate that

[37] After the line-level release was implemented in the summer of 2015.
[38] This is an estimated weighted average for import lines covered by this proposed regulation.
[39] We model this uncertainty as a uniform distribution with a minimum of zero percent (no cases) and a maximum of 100 percent (all cases).
[40] We use a range of 0 to 7 percent annual rate of return on investment [22], [23], which equals a daily rate of 0 to 0.02 percent (0.000192 = 0.07/365).

the cost savings to the entire industry could reach $12 million in the first year. We assume that in the steady state this benefit would increase at the same rate as the annual rate of import lines increase and that these cost savings would reach $22.3 million by the year twenty (Table 12). These cost savings reflect an approximate estimate of profits and sales that would no longer be lost because of possibly faster 'may proceed' outcomes; there may be additional cost savings from possibly reduced warehousing and personnel expenses that we are 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, so we are explicitly seeking comment on these cost savings.

Table 12. Potential undiscounted cost savings from reduced time between import entry submission and 'may proceed' (in $millions)

Year	Cost Savings
1	$12.0
2	$12.4
3	$12.8
4	$13.2
5	$13.7
6	$14.1
7	$14.6
8	$15.1
9	$15.6
10	$16.1
11	$16.6
12	$17.2
13	$17.7
14	$18.3
15	$18.9
16	$19.6
17	$20.2
18	$20.9
19	$21.6
20	$22.3
Total	$332.8

Having a more predictable import process may also be important for importers and other businesses that are involved in the import process.[41] 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 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 requirements proposed by this rule, we believe, would allow them to improve upon their usual and customary business practices, but we are unable to quantify these process improvements. We ask for comments and additional information that would allow us to quantify these benefits to the industry.

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

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 remained largely unchanged. For example, in just 5 years between 2010 and 2015, the total number of imported lines that would be impacted by this proposed rule increased from

[41] 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 more predictable import processing time importers could potentially adjust their shipping schedules to better match the cargo delivery date to an estimated entry release date.

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 16.7 million lines in 2014 [8].[42] Overall, according to FDA's internal data, by 2015 medical devices accounted for more than 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, e.g. [14, p. 43]. Having a more efficient automated imports admissibility process such as ACE 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 responsibility of ensuring the safety of all imported 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].

Data errors in import entry requests submitted via ACS often include 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 requests submitted via ACS [15]. In a number of cases, data were not transmitted at all; for example, submissions lacked registration

[42] 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.

and listing information, or were not transmitted correctly. 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. Missing or inaccurate data submitted to FDA often leads to delays in the admissibility review process because FDA employees must manually review entry requests.

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

With this proposed rule, therefore, FDA has decided to identify the information that would 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 the proposed 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 and safer imports

With this proposed rule, FDA gives importers greater responsibility for ensuring the safety of the FDA-regulated products they bring into the U.S. The information that import entry filers would be required to submit into ACE will help ensure that imported cargo meets the standards for admissibility and are as safe as domestically produced FDA-regulated products. For example, according to FDA's internal data, in 2014 there were about 483 import recalls that involved 848 FDA-regulated products that belong to product categories that would be covered by this proposed 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 proposed regulation will help FDA reduce public health risk associated with FDA-regulated imports. Here is one example of the issues that the information mandated by this proposed rule would help in addressing.

- For medical devices, for example, mandatory submission of the Device Listing Number in ACE would 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 US 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.
- Economically motivated adulteration, for example, may present public health risk. The proposed regulation will mandate that filers submit into ACE FDA Line Value and Quantity information, which could be used by the Agency to determine the public health risk of the

cargo submitted for entry. By analyzing the provided value and quantity information, FDA would be able to identify patterns of potential economically motivated adulteration. For example, if a pound of saffron or a package of drug that is expensive in the U.S. was valued at $1.00, the inconsistency between the value and quantity of that commodity may indicate that there is an issue with that import entry line.

FDA lacks information about the size of the counterfeit market or the severity of misbranding of FDA-regulated imports entering the U.S. We request comment and information that would aid in the quantification of any benefits related to these issues.

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 any efforts on the part of FDA to clarify the import admissibility process. By proposing to revise sections 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 proposing revisions to clarify the term owner or consignee and the notices on sampling, this rule and FDA can provide additional information to the industry that increases the clarity of FDA's import admissibility process. By clarifying that importers of record of human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Services Act and 21 CFR part 1271, unless exempted, would be required to submit the applicable data elements included in the proposed rule in ACE, FDA can provide additional information to the industry that increases the clarity of FDA's import admissibility process for these products. 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, but expect these benefits to be positive [16].

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

Additional cost savings from this 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 destruction. Currently, 21 CFR 1.94 states that FDA shall give a written notice to the owner or consignee. 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 would 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 receiving a notice on refusal of admission by some owners or consignees. Compared to receiving such notice by mail, which takes typically 5-6 days [16], electronic notice provides virtually instant notification. This 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 would result in an average 5.5 days of time savings, which we convert to warehouse storage cost savings for those owners and consignees that would receive a notice on refusal of admission. The cost of the space needed to store each import product line may be $50-$150 per day for typical shipments [17], with the best cost estimate of $100.[43]

According to FDA internal data [1], in 2015 there were 74,022 imports cases that required an FDA notice of action on potential refusal of admission, 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 [18].[44,45] Because FDA intends to combine into a single notice the notice on potential refusal with the notice on potential destruction for drugs under the FD&C Act, we only count the number of notices on potential refusals in our estimates of cost savings. Under the assumption that about 50 percent of imports that receive notices on potential refusal 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[46], 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

[43] 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.
[44] The RIA for the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule doesn't account for electronic notification [25].
[45] We do not have any information to make an assumption on whether the number of these cases would increase or decrease in the future.
[46] We estimate upper and lower range using Monte Carlo simulations.

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 on hearing on refusal by electronic mail instead of regular mail. We therefore request comment on possible cost savings (in dollars) from revisions to 21 CFR 1.94 that would allow FDA to electronically notify the owner or consignee of a hearing on refusal of admission or destruction.

Cost savings to FDA would include time saved to issue notices electronically. We estimate that currently it takes one FDA GS-10-5 level[47] employee between 5 and 7 minutes [16] 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 proposed rule is implemented, we estimate it would 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 would result in an average of 5 minute savings per notice. In 2015, there were 74,022 imports cases that required a notice of action on potential refusal of admission and 10,591 cases that would have potentially require 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], [18].[48] As already stated above, because FDA intends to combine into a single notice the notice of a hearing on refusal with the notice of a hearing on destruction for drugs under the FD&C Act, we only count the number of notices of a hearing on refusals in our estimates of cost savings.

We assume that in some circumstances a hard-written copy may be necessary instead of an electronic notification and estimate that in 90 percent of cases such notice would be issued

[47] We use this wage rate for GS-10-5 level FDA employee because it was also used in the PRIA for the Administrative Destruction of Certain Drugs Refused Admission to the United States proposed rule [26].
[48] The RIA for the Administrative Destruction of Certain Drugs Refused Admission to the United States final rule doesn't account for electronic notification [25].

electronically. The base wage cost of $25.61 per hour for a GS-10-5 level employee is taken from the OPM GS hourly table [19] and increased by 100 percent to $51.22 to include locality and overhead costs, such as office space, health insurance, and retirement benefits. The total estimated cost savings, therefore, are $0.3 million per year (74,022 notices x 0.90 x (6 minutes – 1 minute) / 60 minutes) x $51.22 hourly wage = $0.3 million).

D. Option 2 – All ACE Data Elements Listed in This Proposed 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 information for the data elements currently listed in this proposed rule. The total cost and the per firm cost of this option depends on whether businesses submit some or all of the currently voluntary information. A business has an incentive to only submit voluntary information into ACS/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 assure 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. 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 assuring the safety of imports and 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 Proposed Rule, but for Fewer Import Product Categories

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

This option lowers the costs of this proposed regulation. We estimate that total annual costs for this option are $76.0 million in the first year and between $69.8 million and $125.9 million in years 2 to 20 (Table 13). Annualized over 20 years, costs for this option would be $91.4 million with a 3 percent discount rate and $88.0 million with a 7 percent discount rate (Table 13). Compared with the proposed regulation, annualized costs for Option 3 are lower by about $24 million at a 3 percent discount rate and by $23 million at a 7 percent discount rate.

Table 13. 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	$1.8	$74.0	$76.0	$73.7	$71.0
2	$0.0	$1.8	$67.9	$69.8	$65.8	$60.9
3	$0.0	$1.9	$70.2	$72.1	$66.0	$58.8
4	$0.0	$1.9	$72.6	$74.5	$66.2	$56.8
5	$0.0	$2.0	$75.0	$77.0	$66.4	$54.9
6	$0.0	$2.1	$77.5	$79.5	$66.6	$53.0
7	$0.0	$2.1	$80.1	$82.2	$66.8	$51.2
8	$0.0	$2.2	$82.7	$84.9	$67.0	$49.4
9	$0.0	$2.3	$85.5	$87.8	$67.3	$47.7
10	$0.0	$2.4	$88.3	$90.7	$67.5	$46.1
11	$0.0	$2.4	$91.3	$93.7	$67.7	$44.5
12	$0.0	$2.5	$94.3	$96.8	$67.9	$43.0
13	$0.0	$2.6	$97.5	$100.1	$68.1	$41.5
14	$0.0	$2.7	$100.7	$103.4	$68.4	$40.1
15	$0.0	$2.8	$104.1	$106.8	$68.6	$38.7
16	$0.0	$2.9	$107.5	$110.4	$68.8	$37.4
17	$0.0	$3.0	$111.1	$114.1	$69.0	$36.1
18	$0.0	$3.1	$114.8	$117.9	$69.2	$34.9
19	$0.0	$3.2	$118.6	$121.8	$69.5	$33.7
20	$0.0	$3.3	$122.6	$125.9	$69.7	$32.5
Total Years 1 to 20				$1,885.3	$1,360.2	$932.4
Annualized Total Over 20 Years					$91.4	$88.0

We also estimate that total annual benefits for this option are $26.4 million in the first year and between $26.6 million and $31.4 million in years 2 to 20 (Table 14). Annualized over 20 years, benefits for this option would be $28.4 million with a 3 percent discount rate and $28.1 million with a 7 percent discount rate (Table 14). Compared with the proposed regulatory option, annualized benefits for Option 3 are lower by about $8.4 million at a 3 percent discount rate and by $8.0 million at a 7 percent discount rate.

Table 14. Quantifiable Benefits of Option 3 (Fewer Covered Import Lines) Over 20 Years (in $millions)

Year	Undiscounted Regulatory Benefits (Quantifiable Only)				Present Value with Discount Rate	
	Benefit to the industry from faster 'may proceed'	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	$5.8	$20.4	$0.3	$26.4	$25.7	$24.7
2	$6.0	$20.4	$0.3	$26.6	$25.1	$23.3
3	$6.2	$20.4	$0.3	$26.8	$24.6	$21.9
4	$6.4	$20.4	$0.3	$27.0	$24.0	$20.6
5	$6.6	$20.4	$0.3	$27.2	$23.5	$19.4
6	$6.8	$20.4	$0.3	$27.5	$23.0	$18.3
7	$7.1	$20.4	$0.3	$27.7	$22.5	$17.2
8	$7.3	$20.4	$0.3	$27.9	$22.0	$16.3
9	$7.5	$20.4	$0.3	$28.2	$21.6	$15.3
10	$7.8	$20.4	$0.3	$28.4	$21.1	$14.4
11	$8.0	$20.4	$0.3	$28.7	$20.7	$13.6
12	$8.3	$20.4	$0.3	$29.0	$20.3	$12.9

Year	Undiscounted Regulatory Benefits (Quantifiable Only)				Present Value with Discount Rate	
	Benefit to the industry from faster 'may proceed'	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%
13	$8.6	$20.4	$0.3	$29.2	$19.9	$12.1
14	$8.9	$20.4	$0.3	$29.5	$19.5	$11.4
15	$9.2	$20.4	$0.3	$29.8	$19.1	$10.8
16	$9.5	$20.4	$0.3	$30.1	$18.8	$10.2
17	$9.8	$20.4	$0.3	$30.4	$18.4	$9.6
18	$10.1	$20.4	$0.3	$30.8	$18.1	$9.1
19	$10.5	$20.4	$0.3	$31.1	$17.7	$8.6
20	$10.8	$20.4	$0.3	$31.4	$17.4	$8.1
Total Years 1 to 20				$573.9	$423.1	$298.0
Annualized Total Over 20 Years					$28.4	$28.1

Although this approach would reduce the total cost of the rule, it would also introduce inconsistency in terms of data that FDA would have in hand in case of a product recall of non-covered imports. 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 on hearing of refusal of admission or 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 are currently collected in ACS and new voluntary data elements that FDA

would request in ACE. Under this option, FDA would mandate that the industry submits through ACE all the information for the data elements currently listed in this proposed rule, along with all the voluntary and optional elements listed in FDA's ACE Supplemental Guide [20].

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 $192.1 million in the first year and between $176.5 million and $318.5 million in years 2 to 20 (Table 15). Annualized over 20 years, costs for this Option 4 would be $231.3 million with a 3 percent discount rate and $222.7 million with a 7 percent discount rate, which is about $116 million - $111 million more than the costs for the proposed regulation (Table 15).

Table 15. Total Costs of Option 4 (All Elements, Including Those That are Currently Collected will be Mandatory) 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	$0.5	$4.4	$187.2	$192.1	$186.5	$179.5
2	$0.0	$4.6	$171.9	$176.5	$166.4	$154.2
3	$0.0	$4.7	$177.7	$182.4	$166.9	$148.9
4	$0.0	$4.9	$183.6	$188.5	$167.5	$143.8
5	$0.0	$5.1	$189.7	$194.8	$168.0	$138.9
6	$0.0	$5.2	$196.0	$201.2	$168.5	$134.1
7	$0.0	$5.4	$202.6	$208.0	$169.1	$129.5
8	$0.0	$5.6	$209.3	$214.9	$169.6	$125.1
9	$0.0	$5.8	$216.3	$222.1	$170.2	$120.8
10	$0.0	$6.0	$223.5	$229.5	$170.7	$116.6
11	$0.0	$6.2	$230.9	$237.1	$171.3	$112.7
12	$0.0	$6.4	$238.7	$245.0	$171.9	$108.8

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%
13	$0.0	$6.6	$246.6	$253.2	$172.4	$105.1
14	$0.0	$6.8	$254.8	$261.6	$173.0	$101.5
15	$0.0	$7.0	$263.3	$270.3	$173.5	$98.0
16	$0.0	$7.3	$272.1	$279.4	$174.1	$94.6
17	$0.0	$7.5	$281.1	$288.7	$174.6	$91.4
18	$0.0	$7.8	$290.5	$298.3	$175.2	$88.2
19	$0.0	$8.0	$300.2	$308.2	$175.8	$85.2
20	$0.0	$8.3	$310.2	$318.5	$176.3	$82.3
Total Years 1 to 20				$4,770.1	$3,441.5	$2,359.1
Annualized Total Over 20 Years					$231.3	$222.7

Such an approach would increase the total cost of the rule without significantly increasing the additional benefits. Currently, a business has an incentive to submit voluntary information into ACS/ACE if it believes that FDA values this voluntary information and that FDA would 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 faster 'may proceed' decision by FDA. Regardless of whether they value a faster 'may proceed' decision, under Option 4 all businesses would have to bear the additional costs to learn about the proposed regulation and to prepare, enter and submit into ACE all data elements listed in this proposed regulation and in the FDA's ACE Supplemental Guide [20], including elements that are voluntary and optional under the proposed rule. Given that not all businesses may value a faster FDA's '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 that can help ensure that imported cargo is as safe as domestically produced FDA-regulated products. However, the added information that is voluntary under Option 1 and would become mandatory under Option 4 may not be powerful enough in influencing the speed of entry review process and the ability for the system to provide an automated '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 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 proposed regulation (Option 2) would be about $96 million in the first year and between $88 million and $159 million in years 2 to 20. The present discounted value of costs is $1,721 million at 3 percent discount rate and $1,180 million at 7 percent. At a 3 percent discount rate, the annualized costs of the proposed rule, discounted 20 years into the future, would be $115.7 million. For a discount rate of 7 percent, the annualized costs over 20 years would be $111.3 million. The benefits that we were able to quantify would be between $33 million and $43 million. The present discounted value of benefits that we were able to quantify is $547 million at 3 percent and $383 million at 7 percent. At a 3 percent discount rate, the annualized benefits of the proposed rule that we were able to quantify, discounted 20 years into the future, would be $36.8 million. For a discount rate of 7 percent, the annualized quantifiable benefits over 20 years would be $36.1 million.

We incorporated uncertainty into the analysis in our base estimates as presented in the estimated ranges throughout this PRIA 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.[49]
- The number of cases related to hearings on refusal of admission or 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 the proposed 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 cases related to hearings on refusal of admission or destruction for which FDA would provide electronic notice would increase between 0 and 10 percent in the future.
- The number of cases related to hearings of refusal of admission or destruction for which FDA would provide electronic notice would decrease between 0 and 10 percent in the future.

[49] 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 2.5 percent per year, and maximum growth rate of 10 percent per year.

Table 16 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 16 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 cases that would require electronic notification by FDA.

Table 16. Sensitivity Analysis for Assumptions Made for Proposed 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)	$115.7	$224.2	$108.5
The number of import lines will increase at the average rate of 10 percent per year (Benefits)	$36.8	$52.0	-$15.2
The number of import lines will not grow or decline (Costs)	$115.7	$86.1	-$29.6
The number of import lines will not grow or decline (Benefits)	$36.8	$32.6	-$4.2
The number of import lines will decline at the average rate of 5 percent per year (Costs)	$115.7	$58.2	-$57.5
The number of import lines will increase at the average rate of 5 percent per year (Costs)	$115.7	$135.3	$19.6
Increase in the number of cases that would require electronic notification by FDA (Benefits)	$36.8	$48.7	$11.9
Decrease in the number of cases that would require electronic notification by FDA (Benefits)	$36.8	$30.0	-$6.8

III. REGULATORY FLEXIBILITY ANALYSIS

A. Introduction

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. 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 proposed rule would result in a significant impact on a substantial number of small entities, but the impacts are uncertain so we are explicitly seeking comment on the impacts.

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 [21] 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 PRIA, 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 51,341 out of 52,292 importers are small businesses.

FDA does not have detailed information on the approximately 4,010 persons (e.g. importers, customs brokers, and other firms that may be filing entries into ACE) that will be responsible for submitting the information mandated by this proposed 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 3,970 filers (99 percent of all 4,010 filers) are small businesses. We also estimate that these small businesses annually submit entry requests for about 30 percent of import lines that would be covered by this proposed rule, or for about 10.2 million import lines. Based on SBA data [21], businesses in the wholesale trade industry[50] 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 propose that net impact to small businesses covered by this proposed rule would be minimal compared to their annual sales.

C. Cost per Entity

[50] NAICS code 42 - Wholesale Trade.

Small businesses will be affected by this proposed 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 filing 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 4,010 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 $1,951 with a 3 percent discount rate and $1,878 with a 7 percent discount rate. These small businesses would bear the costs of this rule, but also enjoy most of the benefits. The per-importer annualized benefits that we were able to quantify are $620 with a 3 percent discount rate, and $609 with a 7 percent discount rate. Other 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 are presumed to be positive.

VI. 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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