DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Administrative Destruction

Docket No. FDA-2021-N-1348

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The primary public health benefit of the final rule will be the value of preventing additional illnesses or deaths by destroying, rather than returning to the sender, refused devices valued at $2,500 or less, which may pose a public health risk. This benefit will accrue whenever the FDA's existing enforcement tools would not have prevented the violative device from entering the United States market. The estimated primary costs of the final rule include the additional costs to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at International Mail Facilities (IMFs) prior to destruction. There will also be one-time costs to FDA to update its electronic Operational and Administrative System for Import Support (OASIS) and System for Entry Review and Import Operations (SERIO); revise its Regulatory Procedures Manual (RPM), Investigations Operations Manual (IOM), and additional FDA and inter-agency procedures; and train employees on the new procedures. Express couriers will incur one-time costs to read and understand the rule. We estimate that the annualized benefits over 10 years will range from $148,000 to $750,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $317,000. The annualized costs will range from $68,000 to $1.59 million at a 7 percent discount rate, with a primary estimate of $475,000, and from $63,000 to $1.58 million at a 3 percent discount rate, with a primary estimate of $470,000.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are "significant" under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they "have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the [Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities." OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because of the number of expected device destructions per year and the very small value per event, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The 2022 threshold after adjustment for inflation is $177 million, using the 2022 Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits and Costs

The final rule will implement the authority of the United States Food and Drug Administration (FDA) to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been offered for import and refused admission into the United States under the Federal Food, Drug, and Cosmetic (FD&C) Act, by providing notice and opportunity to the owner or consignee to appear and introduce testimony to FDA prior to the destruction. Because the majority of devices offered for import that are valued

at $2,500 or less are shipped via international mail and express couriers, FDA currently intends to implement the final rule at the International Mail Facilities (IMFs) and express couriers. We do not, therefore, consider impacts related to shipments via commercial air, land, and sea ports.[1]

The costs and benefits of the final rule will depend on the number of administrative destructions that FDA orders each year for refused devices valued at $2,500 or less. For our primary estimates, we assume that FDA will order the destruction of 65 percent of refused devices valued at $2,500 or less. We additionally assume that FDA will contract out the act of destruction to a private firm and combine the notice and hearing process for destruction with the notice and hearing process for refusal. We summarize the costs and benefits of the final rule in Table 1.

We estimate that the annualized benefits over 10 years will range from $148,000 to $750,000 at a 7 percent discount rate and a 3 percent discount rate, with a primary estimate of $317,000. The annualized costs will range from $68,000 to $1.59 million at a 7 percent discount rate, with a primary estimate of $475,000, and from $63,000 to $1.58 million at a 3 percent discount rate, with a primary estimate of $470,000.

Over 10 years, the present value of total benefits will range from $1.04 million to $5.27 million at a 7 percent discount rate, with a primary estimate of $2.22 million, and from $1.27 million to $6.39 million at a 3 percent discount rate, with a primary estimate of $2.70 million. The present value of total costs will range from $474,000 to $11.14 million at a 7 percent discount rate, with a primary estimate of $3.33 million, and from $539,000 to $13.49 million at a 3 percent discount rate, with a primary estimate of $4.01 million.

Notwithstanding the quantified estimated benefits described above, the primary benefit of the final rule will be the unquantified value of additional illnesses or deaths averted from destroying, rather than returning, refused devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). Additionally, if a destroyed device is a counterfeit or an otherwise falsified version of an approved or cleared device, the owner of the approved or cleared device may benefit through increased sales, brand value, or research and development funding. The threat of destruction additionally may have a deterrent effect, reducing the amount of adulterated or misbranded (violative) devices that are offered for import into the United States. These benefits will accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the United States market; the current policy for returning refused devices does not preclude the re-importation of the device into the United States in the future. We do not have enough information to quantify these benefits.

[1] Based on internal data, the majority of devices that were offered for import, valued at $2,500 or less, and refused in fiscal year 2022 were shipped via IMF or express courier.

Table 1. Summary of Benefits, Costs, and Distributional Effects of Final Rule (millions of 2022 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/y)[a]	$0.317	$0.148	$0.750	2022	7%	10 years	Benefits include cost savings to express couriers and USPS.
		$0.317	$0.148	$0.750	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative	Benefits of the final rule include the additional illnesses or deaths averted from destroying, rather than returning, refused devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation).						
Costs	Annualized Monetized ($m/y)[a]	$0.475	$0.068	$1.586	2022	7%	10 years	
		$0.470	$0.063	$1.582	2022	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/y)					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized ($m/y)					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: No estimated effect. Small Business: No estimated effect. Wages: No estimated effect. Growth: No estimated effect.							

[a] When calculating annualized benefits and costs, we assume that payments occur at the end of each period. Throughout our analysis, we use "year 1" to represent impacts that occur during the year that the final rule is finalized.

The destruction of refused devices will lessen the costs incurred to export and return refused devices to their country of origin (the current procedure for refused devices valued at $2,500 or less). Express couriers and the United States Postal Service (USPS) will incur quantified cost savings from exporting and returning fewer refused devices, respectively.

Quantified costs of the final rule will include the costs to FDA to destroy, rather than return, refused devices valued at $2,500 or less, and the additional costs to store these devices at

IMFs prior to destruction.[2] FDA will additionally incur one-time costs to update its electronic Operational and Administrative System for Import Support (OASIS) and System for Entry Review and Import Operations (SERIO); revise its Regulatory Procedures Manual (RPM), Investigations Operations Manual (IOM), and additional FDA and inter-agency procedures; and train employees on the new procedures. Express couriers will incur one-time costs to read and understand the rule.

If our assumptions do not hold, FDA may incur additional costs, including costs to purchase equipment to destroy refused devices, costs to train employees administering the destruction of refused devices, costs to separately notify the owners or consignees of refused devices, and costs to prepare for hearings on destruction that the owners or consignees of refused devices request.

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

FDA's proposed rule "Administrative Destruction" (87 FR 60947) was published on October 7, 2022, and its comment period ended December 6, 2022. We describe and respond to comments we received on the Preliminary Regulatory Impact Analysis (PRIA) of the proposed rule in the following paragraphs. We have numbered each comment to help distinguish between the different comment topics. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or the order in which comments were received or topics were discussed in the comment(s).

(Comment 1) We received comments opposing the rule based on our estimates of potential costs being greater than the potential benefits, but other comments supported the rule, including a comment recognizing the difficulty of accurately quantifying the potential human loss, illness, and complications averted with the implementation of the rule. The comment discussed that potential cost estimates are greater than potential benefit estimates due to the difficulty of accurately quantifying the potential human loss, illness, and complications associated with the use of equipment that is faulty or incapable of performing the task it is supposed to perform.

(Response 1) Our estimate of the benefits from the rule does not include those benefits that could not be quantified. We discuss these possible benefits and the difficulties of quantifying these benefits in the analysis. These benefits include, for example, primary benefits to society due to the value of additional illnesses or deaths averted by administrative destruction compared with currently available enforcement and regulatory actions. Also, if destroyed devices are substitutes for legitimate devices, then firms selling the legitimate devices would receive benefits through increased sales. There will also be benefits from deterrence if administrative destruction of

[2] We estimated the quantifiable costs of this final rule based on its annual impact to society. Therefore, the authority provided to FDA by section 801(a) and (c) of the FD&C Act to recoup the costs of storage and destruction from an owner or consignee does not factor into the estimated primary costs of the final rule. Funds charged to and received from the owners and consignees of the destroyed devices will act as a transfer to FDA for reimbursement related to the costs of destroying the device.

refused devices decreases the likelihood that violative devices will be offered for import to the United States in the future.

While the rule will ensure that refused devices offered for import and valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) are permanently removed from commerce in the United States through destruction, we cannot estimate the total potential annual benefits because we cannot measure the effectiveness of current enforcement and regulatory actions. It is also difficult to get an accurate estimate of the prevalence of the illegal device trade and its current impact on consumers, producers, and the economy due to the multiple dimensions that must be considered, including types of devices, consumer substitution for devices purchased on the internet, and the prevalence of counterfeit devices. Even though we cannot quantify some of the main benefits of the rule, we believe that the final rule will benefit public health.

(Comment 2) We received a comment stating there is no evidence that suggests how the return of devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that have been offered for import and refused admission into the United States, is any more harmful than their destruction, or how strong the deterrence effect might be. Thus, the comment asserted that benefits of the rule seem both vague and impossible to quantify, and costs are estimated to outweigh the benefits over an annualized ten-year plan.

(Response 2) We discuss the possible benefits and the difficulties of quantifying some of these benefits in the analysis. These include, for example, benefits from deterrence if administrative destruction of refused devices decreases the likelihood that violative devices will be offered for import to the United States in the future. While the rule will ensure that refused devices offered for import and valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) are permanently removed from commerce in the United States through destruction, we cannot estimate the total potential annual benefits because we cannot measure the effectiveness of current enforcement and regulatory actions. It is also difficult to get an accurate estimate of the prevalence of the illegal device trade and its current impact on consumers, producers, and the economy due to the multiple dimensions that must be considered, including types of devices, consumer substitution for devices purchased on the internet, and the prevalence of counterfeit devices. Even though we cannot quantify some of the main benefits of the rule, we believe that the final rule will benefit public health.

D. Summary of Changes

For this final regulatory impact analysis, we have updated inputs using more recent data, where possible. Specifically, we have updated wages for express couriers, staff from FDA's Office of Regulatory Affairs, and United States Customs and Border Protection staff using 2022 data. We have inflated other inputs to 2022 dollars using the Consumer Price Index. We also

added internal data for fiscal years 2021 and 2022 to our baseline estimates of the average number of device inspections and refusals per year.

II. Final Economic Analysis of Impacts

A. Background

A device is, in part, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of a disease or other condition or in the cure, mitigation, treatment or prevention of a disease, or intended to affect the structure or any function of the body, and that does not achieve its primary intended purposes through chemical action within or on the body or by being metabolized.[3] Articles offered for import which meet the definition of device include devices intended for human or animal use. The device supply chain is global and highly complex. Starting with a device's raw materials, multiple firms in different locations around the world may be responsible for manufacturing, packaging, labeling, and distributing a single device. Devices may enter the United States through an International Mail Facility (IMF), an express courier hub, or a commercial air, land, or sea port of entry. Imported devices account for approximately 30 percent of the United States device market and 48 percent of all FDA commodity imports (Refs. [1], [2]).

1. Current Device Importation Process for International Mail and Express Courier Shipments

Imported devices may enter the United States through a commercial port of entry, an express courier service, or international mail. These devices, which may include finished devices and components of devices, are shipped to the United States for eventual commercial distribution in most cases. Parcels containing devices sent via an express courier service enter the United States through one of the express courier's international hubs, while parcels containing devices sent through the United States Postal Service (USPS) enter the United States through an IMF.

Devices offered for import are subject to refusal of admission if, among other reasons, they appear to be adulterated or misbranded. The owner or consignee of the detained device is issued a Notice of FDA Action for detention which includes instructions on how to request a hearing under 21 CFR 1.94 to contest the basis for the refusal. The owner or consignee also has an opportunity to request to recondition the product to correct the violation.[4] If FDA determines the device is or appears to be adulterated or misbranded, the device is refused admission and the owner or consignee is issued a Notice of FDA Action stating the Agency's decision to refuse some or all of the article(s) listed in the first Notice of FDA Action for detention.[5] Devices that have been refused admission are returned by USPS to the country of origin or exported or destroyed by the express courier within 90 days of the refusal, consistent with section 801(a) of the FD&C Act.

2. Counterfeit Devices

[3] See section 201(h) of the FD&C Act (21 U.S.C. 321(h)).
[4] 21 CFR 1.94; https://www.fda.gov/industry/actions-enforcement/detention-hearing
[5] https://www.fda.gov/industry/actions-enforcement/import-refusals

The term 'counterfeit device' means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.[6] Counterfeit devices can be manufactured from inferior quality components or fake parts containing toxic materials, or packaged with labeling that falsely suggests the device is authorized by FDA. Use of these devices may prevent consumers from receiving the actual treatments they need, or result in injury, permanent disability, or death (Ref. [3]).

3. International Trade and COVID-19

As international trade in devices continues to grow, it is possible that the number of adulterated or misbranded devices offered for import to the United States will also increase.[7] The COVID-19 pandemic provided additional opportunities for foreign entities to attempt to profit from online sales of violative devices to United States consumers.[8]

As we noted in the PRIA, since the onset of the COVID-19 pandemic, FDA has received thousands of reports of violative medical products claiming to mitigate, prevent, treat, diagnose, or cure COVID-19, including illegally marketed test kits and fake or substandard personal protective equipment (PPE) (p.7). As of January 2022, FDA had issued 260 warning letters to sellers of violative devices, including at-home antibody and antigen test kits and products for measuring human body temperature. As of September 2020, FDA refused admission to over 460,000 fraudulent COVID-19 tests across 470 shipments at the United States border. In fiscal year 2021, U.S. Customs and Border Protection (CBP) seized just over 35 million counterfeit N95 face masks. Use of these fraudulent products could lead consumers to unknowingly spread COVID-19 and prevent consumers from seeking treatment for undiagnosed infections.

B. Potential Need for Federal Regulatory Action

FDA's current enforcement tools do not provide adequate assurance that violative devices valued at $2,500 or less and offered for import under section 801(a) of the FD&C Act will not enter the United States' or another country's device supply. Prior to the authority that the final rule will implement, when FDA refused admission to a device valued at $2,500 or less and offered for import under section 801(a) of the FD&C Act, the device would be returned to the country of origin by USPS or exported or destroyed within 90 days of refusal by the express courier. This allows for the possibility that the returned device will be re-imported and enter the United States' or another country's device supply at a later date. To destroy a device, it would have to be seized and condemned under section 304 of the FD&C Act or under CBP's seizure and forfeiture authority, such as 19 U.S.C. §1595a(c).

[6] Section 201(h)(2) of the FD&C Act (21 U.S.C. 321(h)(2)).
[7] The total value of device imports increased by 9.9 percent between 2017 and 2018 to $51.6 billion (Ref. [1]).
[8] COVID-19 is a disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Violative devices might contain inferior quality components or toxic materials, and consumers who use violative devices may suffer injury, permanent disability, or death. In addition, sales of counterfeit devices may result in loss of revenue, loss of market value, and lower investment in research and development to firms producing FDA-approved or FDA-cleared devices.

As the volume of devices shipped to the United States increases, the probability that a package containing a violative device would be selected for review would likely decline due to FDA and CBP resource constraints, increasing the possibility of previously-refused devices entering the United States device market. The destruction of violative devices valued at $2,500 or less will decrease the pool of previously-refused devices available for future entry into the United States device market.

C. Purpose of the Rule

The purpose of the final rule is to implement FDA's authority to destroy a device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation), that has been refused admission into the United States under the FD&C Act, by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. This will provide FDA with an additional enforcement tool to better protect the nation's device supply and the public health.

D. Baseline Conditions

The final rule will provide notice to the owner or consignee and an opportunity for the owner or consignee to appear before the Agency and introduce testimony prior to destruction of their refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). To estimate the net economic impact of this final rule on society, we need to approximate how the final rule will change behavior of consumers, producers, and FDA. The effects of the final rule are estimated relative to a baseline. The baseline represents the state of the world in the absence of the final regulatory action. The current state of regulatory authority over adulterated or misbranded devices offered for import with a value of $2,500 or less is the baseline in this analysis.

Currently, FDA may refuse an imported shipment containing a device valued at $2,500 or less if it appears to violate the FD&C Act.[9] Devices shipped via express courier that are refused admission into the United States are exported or destroyed by the express courier within 90 days of refusal. For devices that are shipped via international mail, USPS returns the parcel to the sender or country of origin. We assume that as a result of the final rule, FDA will use the administrative destruction enforcement tool for 50 percent to 75 percent of refused devices valued at $2,500 or less, with a primary estimate of 65 percent, based on subject matter expertise.

[9] For shipments offered for import via international mail, the USPS routes the parcels to CBP. CBP interdicts certain shipments suspected to contain FDA-regulated products and turns the packages over to FDA for examination and determination of admissibility under the FD&C Act.

In the following sections, we summarize the current number of device inspections and refusals per year and our assumptions regarding the effects of the final rule.

1. Current Device Inspections and Refusals Per Year

To analyze the impact of the final rule, we must first estimate how many times FDA might use administrative destruction. We can approximate the maximum number of times FDA might destroy a device by the number of times FDA has refused the admission of a device valued at $2,500 or less. In Table 2, we present the average refusal numbers for devices valued at $2,500 or less for express couriers and IMFs per year in fiscal years 2019 through 2022 based on internal data. Over this time period, FDA refused admission to an average of 3,066 device imports per year.[10] Approximately 39 percent of the refusals over this time period occurred at IMFs.

Table 2. Average Number of Device Inspections and Refusals Per Year (FY2019–FY2022)

Value	Express Couriers	IMFs	Total
Inspections Per Year	602,103	1,425	603,528
Refusals Per Year	1,859	1,206	3,066
Percentage of Total Refusals Per Year	60.7%	39.3%	100.0%
Percentage of Inspected Devices Refused by FDA	0.3%	84.6%	0.5%

Over the four-year time period, FDA refused approximately 0.5 percent of all imported devices valued at $2,500 or less that it reviewed. FDA refused approximately 0.3 percent of devices at express couriers and 85 percent of devices at IMFs.

In our internal data, combination products are identified as either a drug, a device, or a biologic. For example, a combination product containing a device constituent part and a drug constituent part (such as an albuterol inhaler, a pre-filled syringe, or a drug-coated catheter) would be identified as a device or a drug in our internal data, but not both. Since we only report products that are identified as devices in Table 2, combination products that contain a device but are identified as a drug or a biologic would not be reflected in Table 2 or in our cost and benefit estimates in this analysis. We assume that the impact of not considering these products in our analysis is negligible.

2. Assumptions Regarding the Effects of the Rule

a. Key Assumptions

We make several assumptions to estimate the potential impacts of the final rule. The purpose of this exercise is to reflect all possible uses of the authority. What follows is a list of assumptions that we use to estimate the potential benefits and costs of the final rule, which we present in Sections E and F, respectively:

[10] From FY2019-FY2022, there was average of 1859.25 refusals at express couriers, 1,206.25 refusals at IMFs, and 3,065.5 refusals total. The numbers presented are rounded to the nearest integer.

(a) FDA will destroy 50 percent to 75 percent of the devices that are subject to destruction under the new authority, with a primary estimate of 65 percent.[11]
(b) FDA will bear the costs associated with any destructions of refused devices.
(c) Current and projected costs after refusal:
    i. Refused device parcels at IMFs are currently returned at the expense of USPS. After adoption of the final rule, between 50 percent and 75 percent of the refused device parcels valued at $2,500 or less will be destroyed at FDA's expense instead of being returned by USPS. This will represent a cost to FDA and a cost saving to USPS.
    ii. Refused devices at express courier hubs are currently exported at the expense of the express courier. After adoption of the final rule, between 50 percent and 75 percent of the refused device parcels valued at $2,500 or less will be destroyed at FDA's expense instead of being exported by the express couriers. This will represent a cost to FDA and a cost saving to express couriers.
(d) FDA will contract out any destructions of refused devices valued at $2,500 or less to a private firm, and the method of destruction will be determined by the contractor.
(e) FDA will always combine the notice of destruction with the notice of refusal.
(f) FDA will always combine the opportunity to present testimony regarding destruction with the opportunity to present testimony regarding refusal.

In order to present a number of possibilities, we relax several of these assumptions and discuss the results in Section I.

b. Effects for Commercial Land, Air, and Sea Ports

We do not consider cost savings to commercial air, land, and sea ports. Unlike express couriers and USPS who take possession of imported packages, commercial ports do not take possession of the articles. Instead, the importer at a commercial port has possession of the detained articles while admissibility determinations are pending.

The value of violative products is not appropriate to include in a benefit-cost analysis because a violative product has zero value. Therefore, importers of violative products that are refused entry to the United States will lose a product with zero value no matter if the point of entry is through an express courier hub, an IMF, or a commercial port. If FDA takes charge of disposing of refused devices at commercial ports, FDA will bear the cost of destruction. However, since there are currently no plans for FDA to implement the final destruction authority outside of express couriers and IMFs, we do not consider the costs to FDA to destroy any refused devices at commercial land, air, and sea ports in this analysis.

E. Benefits of the Rule

[11] We base this assumption on destructions for refused drugs and conversations with subject matter experts. Across all IMFs, FDA destroyed 77% of refused drugs in fiscal year 2020, 86% of refused drugs in fiscal year 2021, and 83% of refused drugs in fiscal year 2022. We adopt a lower range for the percentage of refused devices that will be destroyed (50-75%, with a primary estimate of 65%) because we assume FDA will prioritize the destruction of drugs over devices in the future.

Adopting the final rule will provide FDA with another enforcement tool to better protect the United States device supply chain and the public health. Implementing the administrative destruction authority for devices will allow FDA to destroy violative devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) and offered for import once they have been refused admission into the United States. Primary benefits to society will include the value of additional illnesses or deaths averted by administrative destruction compared with currently available enforcement and regulatory actions. If destroyed devices are substitutes for legitimate devices, then firms selling the legitimate devices will receive benefits through increased sales. There will also be benefits from deterrence if administrative destruction of refused devices decreases the likelihood that violative devices will be offered for import to the United States in the future.

While the final rule will ensure that refused devices offered for import and valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) are permanently removed from commerce in the United States through destruction, we cannot estimate the total potential annual benefits because we cannot measure the effectiveness of current enforcement and regulatory actions. It is also difficult to get an accurate estimate of the prevalence of the illegal device trade and its current impact on consumers, producers, and the economy due to the multiple dimensions that must be considered, including types of devices, consumer substitution for devices purchased on the internet, and the prevalence of counterfeit devices. Available estimates are highly sensitive to the assumptions used to calculate the impact.

Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in the probability of the event occurring or the change in cost of the event with each regulatory action. What follows is a qualitative discussion of the types of benefits that may be realized by consumers and producers with finalization of the rule. We end this section with a quantitative discussion of the possible cost savings to express couriers and USPS as a result of implementation of the final rule.

1. Possible Benefits to United States Consumers

Consumers may benefit from the final rule through the reduction in their consumption of devices not approved or cleared in the United States. Devices not approved or cleared for sale in the United States may not be safe or effective. Counterfeit devices may contain inferior quality components or fake parts, which may be toxic. For certain categories of devices (e.g., PPE), quality problems can increase the incidence of disease in others. Consumers who use unsafe or ineffective devices may die, become ill, or remain sick longer than they otherwise would have with the use of safe and effective devices.

Consumers that use ineffective and unsafe devices also waste financial resources on the violative device with little to no benefit and may lose confidence in the healthcare industry. In addition to the direct consequences faced by the consumer of unsafe and ineffective devices, death and unexpected or prolonged illness have negative effects on the finances, quality of life, and productivity of friends and family members. Any reduction in the consumption of violative devices will decrease the likelihood of illness or death.

2. Possible Benefits to United States Device Producers

Imported counterfeit versions of legitimate devices may nonetheless be attractive to American consumers due to their often-lower prices. The purchase of counterfeit devices may result in four negative effects on the device industry:

1. When consumers substitute the counterfeit device for the legitimate device, the producer of the legitimate device sells fewer devices, resulting in lower revenues.
2. Firms must devote resources to defending their brand against counterfeiters with legal counsel, anti-counterfeit investigations, and anti-counterfeiting technologies.
3. Consumers who unknowingly purchase an ineffective, unsafe, or counterfeit device may lose confidence in the legitimate device's manufacturer.
4. The prevalence of counterfeit devices may reduce a firm's desire to invest in the research and development of new devices.

Any reduction in the consumption of unapproved and counterfeit devices may decrease these adverse effects on the device industry.

3. Annual Cost Savings to Express Couriers and USPS

Currently, when a device is refused admission at an express courier hub or an IMF, the device is usually exported by the express courier or returned via USPS. We assume that the express courier initially bears the costs to export a refused device and that USPS bears the costs to return a refused device. The cost of export/return of a device includes the cost for use of physical and human resources. With the adoption of the final rule, we assume that between 50 percent and 75 percent of refused devices valued at $2,500 or less at express courier hubs and IMFs will be destroyed rather than exported or returned each year, and that FDA, not express couriers and USPS, will bear the costs of destruction. This could result in annual cost savings to express couriers and USPS, which will no longer incur these costs, beginning in year 1. To determine the value of these costs savings, we estimate the costs to express couriers and USPS to export/return between 50 percent and 75 percent of the devices valued at $2,500 or less that are currently refused at express courier hubs and IMFs.

a. Cost Savings to Express Couriers

In fiscal years 2019 through 2022, an average of 1,859 device shipments which will be covered under the final rule were refused at express courier hubs each year. We assume that as a result of the final rule, FDA will destroy between 930 to 1,394 of these device shipments.[12] To estimate the cost to express couriers to export a refused device, we reviewed international shipping rates for packages valued at $1 and $2,500 and weighing 1 and 20 pounds for several express couriers and international destinations. We estimate that it costs, on average, between $127 and $436 to mail a package to an international destination from the United States via an express courier hub, with a primary estimate of $213. Therefore, we estimate that it could cost

[12] These values equal 1,859 refused devices × 0.50 and 1,859 refused devices × 0.75, respectively.

express couriers between $118,069 and $608,328 to export these devices.[13] If FDA destroys these refused devices as a result of the final rule, express couriers could have their costs reduced by between $118,069 and $608,328 annually. We summarize these cost savings to express couriers in Table 3.

Table 3. Summary of Cost Savings to Express Couriers

Value	Low Estimate	Primary Estimate	High Estimate
Refused Devices Currently Exported at Express Couriers	1,859	1,859	1,859
Percentage of Refused Devices Destroyed by FDA with the Final Rule	50%	65%	75%
Refused Devices Destroyed by FDA with the Final Rule	930	1,209	1,394
Cost Per Exported Device[a]	$127	$213	$436
Cost Savings to Express Couriers with the Final Rule	$118,069	$257,089	$608,328

[a] We base our low estimate on shipping rates for a 1-pound package valued at $1. We base our high estimate on shipping rates for a 20-pound package valued at $2,500. We base our primary estimate on the average of shipping rates for a 5-pound package valued at $1 and a 5-pound package valued at $2,500.
[b] Inputs are presented rounded for readability. This may cause estimates shown to slightly differ compared to the equations shown in footnotes throughout the document.

b. Cost Savings to USPS

In fiscal years 2019 through 2022, an average of 1,206 device shipments which will be covered under the final rule were refused at IMFs each year. We assume that as a result of the final rule, FDA will destroy between 603 to 905 of these device shipments.[14] To estimate the cost to USPS to return a refused device, we reviewed current USPS shipping rates for packages valued at $1 and $2,500 and weighing 1 and 20 pounds. We estimate that it costs, on average, between $50 and $156 to mail a package to an international destination from the United States via an IMF. Therefore, we estimate that it will cost USPS between $30,408 and $141,327 to return these devices.[15] If FDA destroys these refused devices as a result of the final rule, USPS will have their costs reduced by between $30,408 and $141,327 annually. We summarize these cost savings to USPS in Table 4.

Table 4. Summary of Cost Savings to USPS

Value	Low Estimate	Primary Estimate	High Estimate
Refused Devices Currently Returned at IMFs	1,206	1,206	1,206
Percentage of Refused Devices Destroyed by FDA with the Final Rule	50%	65%	75%
Refused Devices Destroyed by FDA with the Final Rule	603	784	905
Cost Per Returned Device[a]	$50	$76	$156

[13] These values equal 930 destroyed devices × $127 per device and 1,394 destroyed devices × $436 per device, respectively.
[14] These values equal 1,206 refused devices × 0.50 and 1,206 refused devices × 0.75, respectively.
[15] These values equal 603 destroyed devices × $50 per device and 905 destroyed devices × $156 per device, respectively.

Value	Low Estimate	Primary Estimate	High Estimate
Cost Savings to USPS with the Final Rule	$30,408	$59,452	$141,327

[a] We base our low estimate on shipping rates for a 1-pound package valued at $1. We base our high estimate on shipping rates for a 20-pound package valued at $2,500. We base our primary estimate on the average of shipping rates for a 5-pound package valued at $1 and a 5-pound package valued at $2,500.

c. Total Cost Savings

Based on our estimates, total cost savings to express couriers and USPS could range from $148,476 to $749,655 per year beginning in year 1.[16] We estimate the annual costs to FDA to destroy 50 percent to 75 percent of the refused devices currently returned at the expense of express couriers and USPS in Section F2.

F. Costs of the Rule

The final rule will result in costs to FDA that include the annual cost to destroy refused devices at express couriers and IMFs. These costs could begin to accrue in year 1. FDA will also incur one-time costs in year 1 to update OASIS and SERIO; revise its RPM, IOM, and additional FDA and inter-agency procedures; and train employees on the new procedures. We assume that FDA will destroy between 50 percent to 75 percent of adulterated or misbranded devices valued at $2,500 or less that are refused admission into the United States at express couriers and IMFs in each year. Other potential labor and resource costs may be incurred by owners or consignees if the owner or consignee requests a hearing on the refusal and destruction.

The costs in this section represent only the potential negative impacts of the final regulation according to the assumptions in Section D2. Costs that will result from relaxing these assumptions are presented in Section I.

1. One-Time Costs to FDA and Express Couriers

a. Costs to Update OASIS and SERIO

FDA will need to update OASIS and SERIO. FDA anticipates that it will need to add new screens to OASIS and SERIO; new programming logic to OASIS and SERIO to identify devices; and new violation charges for devices to the current list of violation criteria in SERIO. Based on IT labor rates, FDA estimates that it will incur a one-time cost of $150,000 in year 1.

b. Costs to Revise FDA and Inter-Agency Procedures

Portions of several FDA and inter-agency procedures related to the importation of devices will require revisions as a result of the final rule. These include updates to FDA's RPM, IOM, and SERIO Guide; mail baggage instructions for FDA's ORA Compliance Branch; FDA internet and intranet pages; and IMF standard operating procedures (SOPs) and work instructions

[16] These values equal $118,069 + $30,408 and $608,328 + $141,327, respectively.

(WIs). A majority of these revisions will take place using FDA resources. CBP and USPS may also allocate resources to the revisions of the IMF SOPs.

We estimate the value of each FDA, CBP, and USPS representative's time based on the fully loaded hourly wage per full-time equivalent (FTE) employee for each agency. In this analysis, we use fully loaded hourly wage rates of $129.98[17] for FDA, $142.74[18] for CBP, and $50.25[19] for USPS.

FDA estimates it will take a total of 314 FDA FTE hours, 26 CBP FTE hours, and 10 USPS FTE hours to review and revise all import procedures. We estimate that FDA will incur a cost of $40,812, CBP will incur a cost of $3,711, and USPS will incur a cost of $503.[20] Thus, the total one-time cost to update all procedures related to the importation of devices will be $45,026 in year 1.

c. Training Costs

FDA expects that it will need to train approximately 80 staff members on the updates to OASIS and SERIO and the revisions to FDA and inter-agency procedures that we describe in the previous sections. The web-based training will last approximately 3 hours. At an FDA fully loaded hourly wage rate of $129.98, the total cost of the training will be approximately $31,194.[21] FDA will hold this separate training in year 1 only. In the future, existing training sessions will incorporate the new processes. Therefore, we consider this to be a one-time cost.

d. Costs to Read and Understand the Final Rule

We assume that each of the 52 express courier hubs operating in the United States in fiscal years 2019 through 2022 could incur a one-time cost to read and understand the final rule in year 1.[22] We assume that 1 to 3 employees from each hub will read the rule's preamble and codified, which contain approximately 6,000 words in total. We also assume that each reviewer will read at the average adult reading speed of 200 words to 250 words per minute. Based on these assumptions, it will take each reviewer between 24 minutes and 30 minutes to read the rule.[23] Given the simplicity of the codified, we do not expect that reviewers will need additional time to understand the rule.

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[17] We use 2022 data on FDA fully loaded Full Time Equivalent (FTE) costs to estimate this fully loaded wage of staff from the Office of Regulatory Affairs (ORA).

[18] We use 2022 data on the total budget authority for CBP from the U.S. Department of Homeland Security's Fiscal Year 2024 Budget-in-Brief to estimate this fully loaded wage of staff from CBP (see https://www.dhs.gov/sites/default/files/2023-03/DHS%20FY%202024%20BUDGET%20IN%20BRIEF%20%28BIB%29_Remediated.pdf).

[19] We inflate the USPS wage that we used in the Final Regulatory Impact Analysis for the 2015 "Administrative Destruction of Certain Drugs Refused Admission to the United States" final rule ($40) to 2022 dollars (Ref. [4]).

[20] These values equal 314 FDA hours × $129.98 per hour, 26 CBP hours × $142.74 per hour, and 10 USPS hours × $50.25 per hour, respectively.

[21] This value is equal to 3 hours × $129.98 per hour × 80 employees.

[22] Costs to read and understand the final rule for IMFs are not included in Section F1d. These costs were included in estimates received from subject matter experts shown in Section F1b.

[23] These values equal 6,000 words ÷ 250 words per minute and 6,000 words ÷ 200 words per minute, respectively.

To value the time for express couriers to read and understand the rule, we adopt the wage from the Bureau of Labor Statistics' (BLS) National Industry-Specific Occupational Employment and Wage Estimates for management occupations (occupation 11-0000) in the couriers and express delivery services industry (NAICS 492100) in May 2022, which is $50.02.[24] We double this wage to account for employee benefits and overhead, yielding a fully loaded hourly wage rate of $100.04 per reviewer.

We estimate that the cost per reviewer to read and understand the final rule will range from $40 to $50 and that total review costs per courier hub will range from $40 to $150.[25] Therefore, we estimate that the total costs for express couriers to read and understand the rule could range from a one-time cost of $2,081 to $7,803 in year 1.[26]

2. Annual Costs to Destroy Refused Devices

a. Annual Costs to Store Devices Awaiting Destruction

We anticipate that the storage time between the decision to destroy a device and the destruction of the device will exceed the storage time between the decision to refuse entry of a device and the device being shipped back to its address of origin. As a result of the final rule, we assume that between 50 percent and 75 percent of refused devices valued at $2,500 or less will be destroyed rather than returned or exported to the shipper or country of origin. This will require devices subject to destruction to be stored between the time when the decision to destroy has been made and the device is transported for destruction.

Based on subject matter expertise on the current frequency of destruction pickups for drugs at IMFs and internal data on examinations and refusals of device parcels, we are able to estimate storage costs for devices awaiting destruction at IMFs. The frequency of pickups at each IMF depends on the number of parcels awaiting destruction and the resources available for storage and transportation. We are not able to estimate storage costs for devices awaiting destruction at express couriers because there is too much uncertainty regarding destruction timelines and the storage of parcels awaiting destruction.

We estimate the number of devices that were refused at each IMF in fiscal years 2019 through 2022 by multiplying the number of reviewed devices valued at $2,500 or less at each IMF by the percentage of inspected devices refused over all IMFs in each year. In 2019, an average of 294 devices were reviewed at each IMF, and 92 percent of reviewed devices were refused at IMFs overall. In 2020, an average of 181 devices were reviewed at each IMF, and 68 percent were refused overall. In 2021, an average of 104 devices were reviewed at each IMF, and 83 percent were refused overall. In 2022, an average of 134 devices were reviewed at each IMF, and 92 percent were refused overall. To estimate how many devices will be stored at each IMF

[24] https://www.bls.gov/oes/2022/may/oessrci.htm
[25] These values equal 1 employee × $100.04 per hour × 0.40 hours and 3 employee × $100.04 per hour × 0.50 hours, respectively.
[26] These values equal $40 × 52 express courier hubs and $151 × 52 express courier hubs.

prior to destruction annually, we apply our assumption that between 50 and 75 percent of refused devices will be destroyed to the average number of device refusals per year per IMF.

We estimate the number of additional storage days necessary for destroyed devices at IMFs. We compare the expected number of days a refused device will be stored between the decision to destroy the device and the destruction of the device with the number of days refused devices are currently stored between the decision to refuse entry of the device and the device being shipped back to its address of origin.

Currently, when a device offered for import is refused admission into the United States, the device is returned to USPS or CBP for shipment to the address of origin within 5 business days of the admissibility decision. Per expertise from subject matter experts, after a notice of destruction is issued for a refused device offered for import at an IMF, it will be stored at the IMF facility for at least 10 business days. Therefore, we base our low estimate of the difference in storage days for devices awaiting destruction and devices awaiting shipment at each IMF on the difference in these estimates, or 5 business days (i.e., 10 business days for pickup for destruction minus 5 business days for return shipment).

For each IMF, our high and primary estimates of the difference in storage days for devices awaiting destruction and devices awaiting shipment are derived from the current frequency of pickups for destroyed drugs. Currently, the frequency of pickups for destroyed drugs across IMFs ranges from 6 weeks to 4 months, depending on volume. For our high estimates, we assume a decision to destroy a device that occurs shortly after a pickup is scheduled, and thus the device will be stored until the next pickup. Thus, we assume that the storage time will equal the pickup frequency in days for each IMF minus 5 business days. The primary estimate of storage days for each IMF represents the midpoint of approximate pickup frequency minus 5 business days. For instance, for an approximate pickup frequency of every 4 months, the primary estimate of storage days will be approximately 61 days (or 2 months) minus 5 business days.[27]

We estimate that the opportunity cost of the space needed to store each refused device will range from $7.50 to $18.84 per day per device.[28] Multiplying the amount of storage days by the estimated costs of storage per day per device, we estimate that annual costs will range from $29,503 to $1.54 million with a primary estimate of $433,906.[29] The annual additional costs of storage for devices awaiting destruction at IMFs are shown in Table 5. We assume that these costs will be borne by FDA or CBP, depending on which agency is renting the storage space.

[27] We assume that each month contains 4.345 weeks on average, or 30.417 days.

[28] The low estimate equals the per day storage cost based on an internet search (see http://www.warehouseservice.com/generalorder.htm). For the high estimate, we inflate the high estimate in the Final Regulatory Impact Analysis for the 2015 "Administrative Destruction of Certain Drugs Refused Admission to the United States" final rule ($15) to 2022 dollars (Ref. [4]).

[29] These values equal 3,934 storage days × $7.50 storage fees per day, 81,920 storage days × $18.84 storage fees per day, and 32,942 storage days × $13.17 storage fees per day, respectively.

Table 5. Annual Additional Storage Costs at IMFs for Devices Awaiting Pickup for Destruction

Value	Low Estimate	Primary Estimate	High Estimate
Total Storage Days	3,934	32,942	81,920
Storage Fees Per Day, Per Device	$7.50	$13.17	$18.84
Total Additional Annual Storage Costs	$29,503	$433,906	$1,543,690

b. Annual Costs to FDA to Transport and Physically Destroy Refused Devices

Under the final rule we assume that between 50 percent and 75 percent of refused devices valued at $2,500 or less at express courier hubs and IMFs will be destroyed rather than exported or returned each year, and that FDA, not express couriers and USPS, respectively, will bear the costs of destruction. In this section, we estimate the annual costs to FDA to destroy these devices.

The cost associated with the destruction of a device includes the cost for use of physical and human resources. We assume that FDA will contract out the act of destruction to a private firm, and that the method of destruction will be determined by the contractor. We estimate the contracted cost to FDA to destroy refused devices will be approximately $5 per device. We base this estimate on the contracted costs of destruction for refused drugs in fiscal year 2021.[30]

In fiscal years 2019 through 2022, an average of 1,859 device shipments were refused at express courier hubs each year. We assume that FDA will destroy between 930 to 1,394 of these device shipments as a result of the final rule.[31] Therefore, we estimate that the physical cost of destroying refused devices at express courier hubs per year will range from $4,652 to $6,978.[32]

In fiscal years 2019 through 2022, an average of 1,206 device shipments were refused at IMFs each year. We assume that FDA will destroy between 603 to 905 of these device shipments as a result of the final rule.[33] Therefore, we estimate that the physical cost of destroying refused devices at IMFs per year will range from $3,018 to $4,527.[34]

We assume refused devices to be destroyed will be picked up by the contractor in truckloads and that the cost of transporting the refused device will not be included in the physical cost of destruction. However, we do not anticipate FDA to incur costs associated with transportation of devices. Based on subject matter expertise, we assume that FDA will not require additional pickups to transport refused devices to the contractor for destruction; we assume that these pickups could be incorporated into existing pickups for refused drugs. In the Final Regulatory Impact Analysis for the 2015 "Administrative Destruction of Certain Drugs Refused Admission to the United States" final rule, we estimated transportation costs for pickups of refused drugs (Ref. [4]). To avoid double counting this impact, we assume that the incremental cost to transport refused devices to the contractor will be $0 per device. Therefore,

[30] To obtain this estimate, we divided the total projected contracted costs of destruction for refused drugs in fiscal year 2021 by the average number of destroyed drugs in fiscal years 2019 and 2020.
[31] These values equal 1,859 refused devices × 0.50 and 1,859 refused devices × 0.75, respectively.
[32] These values equal 930 refused devices × $5 and 1,394 refused devices × $5, respectively.
[33] These values equal 1,206 refused devices × 0.50 and 1,206 refused devices × 0.75, respectively.
[34] These values equal 603 refused devices × $5 and 905 refused devices × $5, respectively.

we estimate that FDA will incur zero transportation costs for IMFs and for express courier hubs each year. However, we assume costs will be incurred for additional storage of refused devices awaiting transportation for destruction, which we discussed in the previous section. Due to data limitations, we are only able to estimate these additional storage costs at IMFs.

c. Total Annual Costs to Destroy Refused Devices

The total annual cost of destroying the refused devices valued at $2,500 or less will equal the sum of the contracted costs of physical destruction, and the cost of storing the refused devices awaiting destruction. We estimate that the total annual cost to destroy refused devices at express courier hubs and IMFs, and to store refused devices awaiting destruction at IMFs will range from $37,173 to $1.56 million.[35]

Taking into account the estimated cost savings to USPS in Section E3, we estimate that the total net annual effect on the public sector from destroying 50 percent to 75 percent of refused devices valued at $2,500 or less will range from a cost of $6,766 to a cost of $1.41 million.[36]

3. Other Possible Enforcement or Regulatory Costs

Differences in other enforcement or regulatory costs associated with refusals and administrative destruction actions may also be relevant to this analysis. These costs include the costs to FDA and owners or consignees of the device associated with preparing for the administrative destruction action, as well as the storage costs to FDA associated with holding the device before it is destroyed. We do not include the costs of preparing for the decision that a refused device should be destroyed because we assume that the FDA compliance officer will make the decision to pursue destruction at the same time as the decision to pursue refusal of the product, and that the destruction notice and proceedings will be combined with the refusal notice and proceedings.

4. Summary of Total Net Costs

In Table 6, we summarize the quantifiable net total costs that may result with the implementation of the final rule based on the assumptions presented in Section D2. In this table, negative costs (presented in parentheses) represent positive cost savings to society. Cost savings may accrue in cases where the cost of destroying the refused device is less than the cost of returning the refused device to its country of origin or exporting it, which is the current procedure.

[35] The low estimate equals approximately 3,065 refused devices × 50 percent × $5 + $29,503. The high estimate equals approximately 3,065 refused devices × 75 percent × $5 + $1,543,690.

[36] These values equal the $7,670 cost to FDA to destroy each year + the $29,503 cost to store each year − the $30,408 cost to USPS to return each year, and the $11,505 cost to FDA to destroy each year + the $1,555,195 cost to store each year − the $141,327 cost to USPS to return each year, respectively.

Table 6. Summary of Net Total Costs of the Final Rule

Value	Low Estimate	Primary Estimate	High Estimate
Annual Express Courier Costs[a]	($118,069)	($257,089)	($608,328)
Annual USPS Costs[a]	($30,408)	($59,452)	($141,327)
Annual FDA Costs	$37,173	$443,877	$1,555,195
Net Annual Costs[a]	**($111,303)**	**$127,336**	**$805,540**
One-Time Costs for IT Updates	$150,000	$150,000	$150,000
One-Time Costs for FDA Import Operations Revisions	$45,026	$45,026	$45,026
One-Time FDA Training Costs	$31,194	$31,194	$31,194
One-Time Express Courier Costs to Read and Understand Rule	$2,081	$4,624	$7,803
Net One-Time Costs	**$228,301**	**$230,844**	**$234,023**
Annualized Net Total Costs[a,b] – 3% Discount Rate	**($85,319)**	**$153,610**	**$832,175**
Annualized Net Total Costs[a,b] – 7% Discount Rate	**($80,925)**	**$158,053**	**$836,680**

[a] We display negative costs (positive cost savings) in parentheses.
[b] We estimate annualized net total costs using a 10-year time horizon.

We estimate that implementing the final rule could result in net annual costs ranging from a cost saving of $111,303 to a cost of $805,540 beginning in year 1. This range represents our best estimate given the information available and the assumptions in Section D2. FDA additionally will incur one-time costs to update OASIS and SERIO, revise import operations, and train FDA employees on the OASIS and SERIO updates and revised procedures. Express couriers will incur a one-time cost to read and understand the rule. We estimate that the sum of one-time costs to FDA and express couriers in year 1 could range from $228,301 to $234,023.

We estimate that the annualized net total costs of the final rule over 10 years could range from a cost saving of $85,319 to a cost of $832,175 at a 3 percent discount rate and from a cost saving of $80,925 to a cost of $836,680 at a 7 percent discount rate.

There are additional uncertainties associated with these cost estimates that are not reflected in the ranges in Table 6. We do not include additional costs to FDA associated with notifying the owner or consignee of the refused device, storing the refused device, and preparing for hearings on destruction when requested by owners or consignees because we assume that the process of notifying, storing, and providing the opportunity to appear and introduce testimony on the destruction of a device will be combined with the process of notifying, storing, and providing the opportunity to appear and introduce testimony on the refusal of a device. In Sections I and J, we relax our assumptions and present alternative scenarios with their associated costs and benefits in order to reflect all possible uses of this authority.

G. Distributional Effects

Currently, devices at IMFs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that have been offered for import and refused admission into the United States under the FD&C Act are returned to USPS for shipment to the address of origin. USPS bears the burden of returning these devices with no reimbursement from FDA. We assumed between 50 percent and 75 percent of these devices will be destroyed at

FDA's expense as a result of the final rule. This will represent a transfer of resources between government agencies.

In addition, under section 801(a) and (c) of the FD&C Act, owners or consignees of destroyed devices are liable for the costs of destroying and storing the device prior to destruction. If funds are charged to and received from the owners and consignees of the destroyed device, they will act as a transfer to FDA for reimbursement related to the costs of destroying the device.

H. International Effects

The device industry is global, with manufacturing and consumption of a product often taking place in different parts of the world. The final rule will implement the authority for FDA to destroy devices valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that have been refused. Foreign firms offering compliant devices for import to the United States will not be affected by this final rule. It is unlikely that the final rule will alter the current mix of foreign and domestic manufacturing for the affected products.

I. Uncertainty and Sensitivity Analysis

In this section, we relax some of our assumptions presented in Section D2 to address uncertainties regarding the costs of the final rule that we do not consider in our primary analysis. Estimates in Section 1 should be considered *in lieu of* the cost estimates in Table 6, and estimates in Section 2 should be considered *in addition to* the cost estimates in Table 6.

1. FDA Implements Destruction Authority at IMFs Only

It is possible that FDA's destruction authority will be initially operationalized for devices at IMFs only. In this scenario, we assume that FDA will fund the destruction of between 50 percent and 75 percent of refused devices valued at $2,500 or less at IMFs, but that all refused devices at express courier hubs will continue to be exported at the expense of the courier (the current procedure for refused devices valued at $2,500 or less). Thus, we estimate that FDA will destroy between 603 and 905 devices in total per year.[37] In this scenario, we also assume that express couriers will no longer bear costs to read and understand the rule. We do not relax any of our other assumptions from Section D2.

In Table 7, we summarize the annualized net total costs of the final rule over 10 years if FDA chooses to implement its destruction authority for devices at IMFs only. We include all quantifiable annual benefits and costs from Sections E and F in the estimates in Table 7; therefore, these estimates should be considered *in lieu of* the primary estimates in Table 6.

[37] We base these values on the average number of refusals at IMFs only in fiscal years 2019 through 2022. These values equal 1,206 refused devices × 0.50 and 1,206 refused devices × 0.75, respectively.

Table 7. Annualized Net Total Costs of Implementing Destruction Authority at IMFs Only

Discount Rate	Estimate	Refused Devices Destroyed by FDA	Annualized Net Total Costs[a]
3%	Low	603	$27,861
	Primary	784	$404,125
	High	905	$1,432,638
7%	Low	603	$32,215
	Primary	784	$408,479
	High	905	$1,436,992

[a] We estimate annualized net total costs using a 10-year time horizon.

2. FDA Does Not Combine Notices and Opportunities to Present Testimony

We also consider the net annual costs associated with relaxing the assumptions that FDA will always combine the notice of destruction with the notice of refusal and FDA will always combine the opportunity to present testimony for destruction with the opportunity to present testimony for refusal (i.e., FDA will hold one hearing on refusal and destruction). We present the net impacts of relaxing these assumptions in Table 8 and discuss the estimates in the subsections that follow. For these scenarios, we continue to assume that we will destroy between 50 percent and 75 percent of refused devices valued at $2,500 or less at express couriers and IMFs; therefore, values in Table 8 should be considered as annual costs *in addition to* the annual cost estimates presented in Table 6.

Table 8. Annual Costs of FDA Not Combining Notices and Opportunities to Present Testimony

Scenario	Low Estimate	Primary Estimate	High Estimate
FDA Sends Separate Notices on Refusal and Destruction	$200,183	$260,863	$301,718
FDA Holds Separate Hearings on Refusal and Destruction	$229,913	$524,923	$866,491

a. FDA Sends Separate Notices on Refusal and Destruction

According to the final rule, FDA will have the option to combine the notices of the intent to destroy and the destruction decision with the notices of the intent to refuse and the refusal decision for each detained device valued at $2,500 or less. Our primary estimates assume that these notices will always be combined. Since there will be no additional cost to combine these notices, we do not include notification as a cost in our primary estimates. However, FDA may choose *not* to combine these notices, and instead send a separate notice for the intent to destroy and the destruction decision.

Under this scenario, we anticipate that FDA will incur labor and resource costs for each correspondence with the owner or consignee of a refused device valued at $2,500 or less that FDA intends to destroy. Labor costs will include the time needed for an FDA employee to create the notice and send it to the owner or consignee. We estimate it will take 0.5 hours of labor for each correspondence at an FDA fully loaded hourly wage rate of $129.98. This gives us an

estimate of $65 in labor costs for each notification.[38] We assume that we will not send the notices electronically and that resource costs, such as ink, paper, and envelopes, will range between $0.31 and $0.63 per notification.[39]

We assume that the total number of devices destroyed by FDA each year will range from 1,533 to 2,299.[40] We additionally assume that FDA will send two notifications per destruction each year. This will result in FDA sending between 3,066 and 4,598 notifications per year. At a labor cost of $65 per notification and a resource cost between $0.31 and $0.63 per notification, we estimate that the total cost of not combining notices of destruction with notices of refusal will range from $200,183 to $301,718 annually beginning in year 1, with a primary estimate of $260,863.[41]

b. FDA Holds Separate Hearings on Refusal and Destruction

According to the final rule, the notice of the intent to destroy a device will specify a time period during which the owner or consignee must notify the Agency that they intend to introduce testimony, either orally or in writing, to challenge the destruction (including the basis for refusal of admission). Currently, an owner or consignee has the opportunity to appear and present testimony to FDA upon refusal. If the notices and hearings on refusal and destruction are combined, we do not anticipate the need for FDA to expend additional resources on the destruction component of a hearing if requested by the owner or consignee, as the FDA will have already anticipated destruction if the device is refused. However, if the opportunities to present testimony on refusal and destruction are not combined—for reasons including FDA receiving additional information about the device after the refusal notice has been issued or the owner or consignee petitioning for and failing to complete reconditioning approved by FDA—FDA may need to hold the refused device for the time period encompassing the required notice and opportunity for the owner or consignee to appear and present testimony on the destruction.

Storing the device will take up space that could be used for other operations. We estimate that the opportunity cost of the space needed to store each refused device will range from $7.50 to $18.84 per day. It is reasonable to expect FDA to allow up to 20 days for the owner or consignee to request to introduce testimony concerning FDA's intent to destroy. If a refused device is held up 20 days, total storage costs for that device will be between $150 and $377, with a primary estimate of $263.[42]

[38] This equals $129.98 per hour × 0.5 hours.
[39] We inflate the resource costs that we used in the Final Regulatory Impact Analysis for the 2015 "Administrative Destruction of Certain Drugs Refused Admission to the United States" final rule (between $0.20 and $0.50) to 2022 dollars (Ref. [4]).
[40] The low estimate equals (1,859 express courier refusals + 1,206 IMF refusals) × 0.5. The high estimate equals (1,859 express courier refusals + 1,206 IMF refusals) × 0.75.
[41] The low estimate equals ($65 in labor costs per notification × 3,066 notifications) + ($0.31 in resource costs per notification × 3,066 notifications). The high estimate equals ($65 in labor costs per notification × 4,598 notifications) + ($0.63 in resource costs per notification × 4,598 notifications).
[42] These values equal $7.50 per day × 20 days, $18.84 × 20 days, and ($7.50 + $18.84) ÷ 2 × 20 days, respectively.

We estimate that FDA will destroy between 1,533 to 2,299 devices valued at $2,500 or less at the IMFs and express courier hubs annually, with a primary estimate of 1,993 devices.[43] Multiplying these values by the total cost to store a device for 20 days, we estimate that the cost of not combining the opportunity to present testimony on refusal and destruction could range from $229,913 and $866,491 each year beginning in year 1, with a primary estimate of $524,923.[44]

J. Analysis of Regulatory Alternatives to the Final Rule

One alternative to the final rule will be to decrease the maximum value of devices that will be subject to the administrative destruction authority from $2,500 to some lower value.[45] This could result in changes to the quantity, type, and average value of refused devices that are destroyed.

Decreasing the maximum value of violative devices subject to destruction will result in fewer devices being eligible for destruction overall. Upon finalization of the rule, this could decrease the expected aggregate value of destroyed devices, quantity of destroyed devices, or both, in each year. Relative to our primary estimates in Section E3, this could, in turn, result in fewer sales gains to device producers and reduce cost savings to express couriers and USPS. Any refused device at an express courier hub or an IMF not destroyed by FDA will need to be exported within 90 days of refusal at the expense of the express courier or returned at the expense of USPS, respectively. If the aggregate value or quantity of destroyed devices decreases, as we expect with this alternative, then the aggregate value and quantity of exported or returned devices will increase, respectively, increasing the export or return burden to express couriers and USPS. This alternative likely would reduce public health benefits to United States consumers if product risk is captured in price.

III. Final Small Entity Analysis

FDA has examined the economic implications of the final rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that will lessen the economic effect of the rule on small entities. Small entities will bear costs from the final rule to the extent that they are responsible for destroyed devices. Because of the number of expected destructions per year and the very small value per event, we certify that the final rule will not have a significant economic impact on a substantial number of small

[43] The low estimate equals (1,859 express courier refusals + 1,206 IMF refusals) × 0.5. The high estimate equals (1,859 express courier refusals + 1,206 IMF refusals) × 0.75. The primary estimate equals (1,859 express courier refusals + 1,206 IMF refusals) × 0.65.

[44] The low estimate equals a $150 cost to store each device for 20 days × 1,533 refused devices. The high estimate equals a $377 cost to store each device for 20 days × 2,299 refused devices. The primary estimate equals a $263 cost to store each device for 20 days × 1,993 refused devices.

[45] The feasibility of this alternative is unclear given that the maximum value is set forth in section 801(a) of the FD&C Act. Section 801(a) of the FD&C Act allows the Secretary of the Treasury to update the maximum value of a product subject to the administrative destruction authority, but by setting a higher amount and only by regulation (pursuant to section 1498(a)(1) of title 19 of the U.S. Code).

entities. This analysis, together with other relevant sections of this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

IV. References

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