DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Administrative Destruction of Certain Drugs Refused Admission to the United States; Final Rule

Docket No. FDA-2014-N-0504

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

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I. Introduction and Summary

A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under 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. Because of the small number of expected destructions each year and the very small value per event, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies 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 $141 million, using the most current (2013) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Comments on the Preliminary Regulatory Impact Analysis

Although we received over 20 comments on the proposed rule, few addressed our preliminary regulatory impact analysis. We discuss those specific comments below. When possible, as discussed in our responses, we adjust our final analysis to take into account these comments.

(Comment 1) One commenter stated that we only quantified the benefits of the proposed rule but did not quantify the costs.

(Response 1) The commenter overlooked the section of the preliminary regulatory impact analysis where we did quantify the costs of the proposed rule. In Section II.F of the preliminary regulatory impact analysis we identified the cost associated with the physical destruction of the refused drug as quantifiable according to the assumptions we list in Section II.D. Other administrative costs were not included because administrative destruction should not add costs in addition to the ones incurred under current enforcement procedures.

In Section II.H of the preliminary regulatory impact analysis we identified several operational alternatives that would increase the cost of the rule if our assumptions are relaxed. In this section we estimated the costs associated with FDA handling each destruction act regionally

(including purchasing the equipment needed to destroy the refused drug, training FDA staff to destroy the refused drug, and the fuel and other resource costs incurred by performing each destruction act), the additional costs of not combining the notice of destruction with the notice of refusal, and the additional costs of not combining the opportunity to testify on refusal and destruction.

(Comment 2) Some commenters suggested that we should include the value of illnesses and deaths to consumers caused by the destruction of drugs that the commenters suggest do not pose a public risk.

(Response 2) The cost of illnesses and deaths caused by the destruction of drugs were not included in the preliminary regulatory impact analysis and are not included in the final regulatory impact analysis because the drugs that are to be destroyed will have already been refused admission into the United States. Currently, owners or consignees do not have access to refused drugs because those drugs are either destroyed by the owner or consignee or they are exported. Certain refused drugs may also be destroyed if they are seized and condemned under FDA's seizure authority, section 304 of the FD&C Act, or if they are seized and forfeited under CBP's seizure and forfeiture authority, such as 19 U.S.C. 1595a(c). Because administrative destruction can occur only after a drug has been refused, the final rule will not impact a consumer's access to that drug.

(Comment 3) We received one comment that points out that we should include the costs of storage or destruction to couriers if couriers will be responsible for storing the refused drug prior to destruction or will be responsible for arranging the destruction of the refused drug.

(Response 3) FDA intends to combine the destruction notice and proceedings with the refusal notice and proceedings. Therefore, we do not anticipate a storage time between the determination to destroy and the destruction of the drug that is different from the storage time between the determination to refuse entry and the drug being shipped back to its address of origin. The costs of destroying the refused drug will be incurred by FDA.

C. Summary of Changes

While we do not make changes to the regulatory impact analysis that are directly related to the comments we received, review of the submitted comments and work on the final rule has led us to re-estimate several costs and also add two costs. A summary of the changes made to the regulatory impact analysis follows.

Changes made to the regulatory impact analysis:

(a) We updated the estimated number of destructions from the commercial ports, express couriers, and International Mail Facilities (IMF) to include the final week of FY2013 and all of FY2014. The estimated total number of expected destructions increased from 12,100 per year to 15,100 per year. This represents a 25 percent increase in the number of expected destructions and can be completely attributed to the average number of refusals at IMFs increasing by approximately 3,000 lines.

(b) In the preliminary regulatory impact analysis we assumed FDA would use a contractor to destroy refused drugs. We estimated the cost to destroy a refused drug based on the refused drug's weight, and we assumed each refused drug would be mailed to the contractor. For the final regulatory impact analysis we anticipate the contract for destruction will instead be a flat, monthly rate and transportation to the contractor will occur in truck loads rather than mailed packages.
    i. We continue to use the assumption that the refused drug will be mailed to one of five FDA import district incinerator operations in the Operational Alternatives section. The difference is because we expect FDA will be able to use a contractor located within a short driving distance from the IMF, Express Courier Hub, or Commercial Port where the drug was refused, but driving the refused drug under the alternatives will not be cost-effective with only five FDA-run destruction facilities.
(c) We lowered our estimates of the costs to the United States Postal Service (USPS) and express couriers of exporting the refused drug to its country of origin.
(d) We added one-time costs for updates to FDA's Operational and Administrative System for Import Support (OASIS) database, revisions to Chapter 9 in FDA's Regulatory Procedures Manual and internal import operations guidelines, and training for FDA personnel.
(e) We changed our estimate of the hourly cost of labor to be based on the hourly rate of a full-time equivalent employee. In the preliminary regulatory impact analysis we estimated the hourly cost of labor based on the Federal Government's General Schedule.

D. Summary of Final Costs and Benefits

The final rule will implement FDA's authority to destroy a drug offered for import that has a value of $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) and that has been refused admission, by providing notice to the owner or consignee and an opportunity to appear and introduce testimony prior to the destruction. Administrative destruction of a refused drug valued at or below $2,500 is a new enforcement tool and we are not able to directly estimate how often it might be used. Our primary estimate assumes all refused drugs valued at $2,500 or less will be destroyed.

The primary public health benefit from adoption of the final rule will be the value of the illnesses or deaths avoided because the Agency destroyed a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that posed a public health risk. Additionally, the rule may benefit firms through increases in sales, brand value, and investment in research and development if the destroyed drug is a counterfeit or an otherwise falsified version of an approved drug. The threat of destruction may also have a deterrent effect resulting in a reduction in the amount of adulterated, misbranded, or unapproved drugs (violative drugs) shipped into the United States in the future. These benefits accrue whenever the Agency's other enforcement tools would not have prevented a violative drug from entering the United States market. The current procedure whereby a drug refused admission might be exported does not ensure that the drug would not be imported into the United States in the future. These benefits are not quantified.

Table 1 – Summary of Net Costs[a, b]

		Lower Estimate	Upper Estimate
Annualized Net Costs	3% Discount Rate	**$89,021**	**-$867,254**
	7% Discount Rate	**$101,228**	**-$855,047**
Public Health Benefits		**Not Quantified**	
Present Value of Discounted Net Costs	3% Discount Rate	**$1,324,401**	**-$12,902,554**
	7% Discount Rate	**$1,072,407**	**-$9,058,383**

[a] Public health benefits were not quantified. Negative values represent cost savings.
[b] We use a 20-year time horizon for this rule.

The estimated primary costs of the final rule include the additional costs incurred by FDA to destroy a refused drug as opposed to the costs related to exportation of the drug and the one-time costs of updating OASIS, revising Chapter 9 in FDA's Regulatory Procedures Manual and internal import operations guidelines, and training for FDA personnel.[1] Our primary estimate assumes all refused drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) will be destroyed, FDA will contract the act of destruction out to another government agency or private firm, and the notice and hearing process for destruction will be combined with the current FDA notice and hearing process for refused drugs. If these do not hold, FDA may incur further costs, such as purchasing equipment to destroy the refused drugs, additional training for employees who will administer the destruction of the refused drugs, additional notification to the owner or consignee of the refused drug, storing the refused drug until it is destroyed, and preparing for a hearing on destruction if requested by an owner or consignee.

The quantifiable net costs to the final rule are summarized in Table 1. Negative values in Table 1 represent cost savings. Cost savings may accrue in cases where the cost of destroying the refused drug is less than the cost of returning the refused drug to its country of origin, which is the current procedure. In all cases, we base the lower estimate of the range on the rates of shipping and destruction costs for 1-pound packages valued at $1, and the upper estimate is based on the rates of shipping and destruction costs for 20-pound packages valued at $2,500.

We estimate the cost of the final rule using an estimated 15,100 administrative destructions performed each year. The assumption that we will destroy all refused drugs represents an upper bound and may not always hold. If FDA chooses to destroy less than all of the refused drugs, all annual costs will decrease but the one-time costs will stay the same.

The Agency estimates the quantifiable net annual effect of the final rule to range from a cost of $54,325 to a cost savings of $901,950. One-time costs of approximately $531,670 will also be incurred. Annualized over 20 years, the final rule is estimated to produce a net effect

[1] We estimated the quantifiable costs of this final rule based on its annual impact to society as a whole. Therefore, the authority provided to FDA by section 801(a) and (c) of the Federal Food, Drug and Cosmetic Act (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 drug will act as a transfer to FDA for reimbursement related to the costs of destroying the drug.

ranging from a cost of $89,021 to a cost savings of $867,254 at a 3 percent discount rate and a cost of $101,228 to a cost savings of $855,047 at a 7 percent discount rate. The present discounted value of the quantifiable net effect over 20 years ranges from a cost of $1,324,403 to a cost savings of $12,902,554 at a 3 percent discount rate and a cost of $1,072,408 to a cost savings of $9,058,383 at a 7 percent discount rate.

We cannot estimate the net benefits of the final rule because we have not quantified the potential health benefits; however, because the final rule likely represents a cost savings and the health benefits, though not quantified, will be positive even if one violative drug that would have caused an adverse event is destroyed rather than entering the U.S. market, the net benefits of the rule are likely positive.

II. Final Regulatory Impact Analysis

A. Background

The drug supply chain is global and highly complex. Starting with its raw materials, a drug may be manufactured, packaged, labeled, and distributed in multiple locations across the globe. The Agency reports that 40 percent of all drugs consumed in the United States are imported (Ref. 1). Drugs manufactured in the United States often contain active pharmaceutical ingredients from overseas. The Agency reports that 80 percent of the active pharmaceutical ingredients (APIs) in drugs consumed in the United States are imported (Ref. 1).

1. Current Drug Importation Process

Foreign drugs may enter the United States several ways: shipping a drug through a commercial port of entry, an express courier service, or via international mail. These drugs may include finished drugs, as well as components of a drug such as APIs, and are shipped to the United States for eventual commercial distribution in most cases. Parcels containing drugs sent via an express courier service enter the United States through one of the express courier's international hubs. Mail parcels containing drugs sent through the USPS enter the United States through an IMF.

Drugs offered for import are subject to refusal of admission if, among other reasons, they appear to be adulterated or misbranded, or appear to be an unapproved drug. The owner or consignee of the detained drug is issued a notice of detention and has an opportunity to respond to the Agency's intended refusal of the drug. If FDA determines the drug is or appears to be adulterated, misbranded, or an unapproved drug, the drug is refused admission and the owner or consignee is issued a Notice of Refusal; otherwise, the drug is released. Drugs that have been refused admission must be exported or destroyed within ninety days of the refusal.

2. International Trade and Internet Pharmacies

As international trade in drugs continues to grow, it is possible the number of adulterated, misbranded, and unapproved drugs, including counterfeit drugs and drugs that are marketed as dietary supplements, offered for import to the United States would also increase. In addition to

the general increase in international trade, the increase in drugs shipped to the United States may partly be due to an increase in the number of internet pharmacies, some of which are not licensed as a pharmacy in the United States. In July 2013, the Government Accountability Office (GAO) issued a report on rogue internet pharmacies. In its report, GAO defined a rogue internet pharmacy as a fraudulent enterprise that operates in violation of federal and/or state law, offers cheap drugs for sale without a prescription that meets federal and state requirements, or operates without a pharmacy license in the United States. According to the GAO report, LegitScript, an online pharmacy verification service that assesses the legitimacy of internet pharmacies, estimated that there were over 34,000 rogue internet pharmacies as of April 2013 (Ref. 2). Approximately 23 percent of American adult Internet users acknowledge purchasing prescription drugs online (Ref. 3). A recent review of internet pharmacies by the National Association of Boards of Pharmacy reveals that approximately 97 percent of the over 10,500 online pharmacies examined did not meet federal and state pharmacy laws or pharmacy practice standards (Ref. 4).

Rogue internet pharmacies are attractive to consumers because they offer for sale prescription-strength drugs at lower prices than licensed pharmacies in the United States, often without requiring a valid prescription. These sites may have the appearance of a legitimate operation due to professional web development, but the safety and effectiveness of the drugs offered for sale on the site may not have been verified. A 2010 report estimates that approximately 17 percent of American adults have purchased a prescription drug online without a prescription (Ref. 5). On the supply side, internet pharmacies are attractive to criminals because they are an easy way to sell fraudulent and illegal drugs with a low risk of being caught but a potentially high reward. Some of the larger rogue internet pharmacies bring in between $1 million and $2.5 million in sales each month (Ref. 6).

3. Counterfeit Drugs

Counterfeit drugs are unapproved drugs that use a counterfeit mark on or in connection with the drug. These drugs can contain too much, too little, or none of the API, they can contain the wrong API, or they can be packaged with labeling that falsely suggests the drug is FDA-approved (Ref. 7). By taking these drugs, consumers may also be prevented from getting the actual medications that they need. The World Health Organization reported in 2012 that less than 1 percent of the drugs available in developed countries, such as the United States, are counterfeit but that approximately 50 percent of the pharmaceuticals on worldwide illegal websites are counterfeit (Ref. 8).

B. Need for Regulation

The primary objective of this final rule is to provide FDA with an additional enforcement tool to better protect the nation's drug supply by implementing an administrative process for the destruction of refused drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) without providing the owner or consignee the opportunity to export the refused drug. Drugs with a value of $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) may enter the United States through an IMF, an express courier hub, or an air, land, or sea port of entry.

Violative drugs might contain too much, too little, or none of the active ingredient, can contain the wrong active ingredient, or can contain a toxic ingredient. Consumers who take violative drugs may get sick or die. For certain classes of drugs (e.g. antibiotics), quality problems can also increase the likelihood of drug resistance. In addition, the sale of counterfeit drugs may result in loss of revenue, loss of market value, and lower investment in research and development.

Prior to the authority that the final rule will implement, when FDA refused admission to a drug offered for import under section 801(a) of the FD&C Act, the drug could be exported within ninety days of refusal. To destroy a drug, it would have to be seized and condemned under section 304 of the FD&C Act or under the U.S. Customs and Border Protection's (CBP) seizure and forfeiture authority, such as 19 U.S.C. §1595a(c).

These enforcement tools may not provide adequate assurance that unsafe or ineffective drugs valued at $2,500 or less would not enter the United States' or another country's drug supply, especially for drug parcels sent through the IMFs. The number of parcels containing these drugs to be examined at IMFs has surpassed the resources available to both CBP and FDA. The United States Postal Inspection Service estimated that the average number of international mail parcels that came into the U.S. through the IMFs from November 1, 2011, to October 31, 2012, totaled nearly 1.2 million every day. It is estimated that the number of such parcels which contain drugs that enter the United States each year through the IMFs is between 20 million and 100 million.

Drugs that have been refused and exported may find their way back to a United States. As the volume of drugs shipped to the United States increases, the probability that a package containing a violative drug would be selected for review would likely decline due to FDA and CBP resource constraints, increasing the possibility of previously-refused drugs entering the United States' drug market.

C. 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 to contest the destruction of certain refused drugs prior to destruction. In order to estimate the net economic impact of this final rule on society, an approximation of the change in behavior of consumers, producers, and FDA is needed. 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 unapproved, adulterated, or misbranded drugs 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 drug, including a biological product, valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) if it appears to violate the FD&C Act. Drugs that are refused admission into the United States must be exported or destroyed within ninety days. We assume FDA may use the final administrative destruction enforcement tool for any refused drug valued at $2,500 or less.

Table 2 – Average Refusal Numbers, FY2011 – FY2014

	Commercial Port	Courier	IMF	Total
Average Number Refused	3,000	2,150	9,950	15,100
Percentage of Refusals	19.81%	14.21%	65.98%	100%
Percentage of FDA Reviews	0.96%	2.05%	80.13%	3.52%

To analyze the impact of the final rule, we must first estimate how many times the Agency might use administrative destruction. We can approximate the maximum number of times FDA might destroy a drug by the number of times FDA has refused the admission of a drug valued at $2,500 or less. Table 2 presents the average refusal numbers for drugs valued at $2,500 or less for air, land, and sea ports of entry (commercial port), express couriers (courier), and IMFs per year over the Fiscal Year 2011 to Fiscal Year 2014 time period. Over this time period, FDA refused an average of approximately 15,100 drug imports per year. Approximately 66 percent of the refusals over this time period occurred at the IMFs.

Over the 4-year time period, FDA refused approximately 3.5 percent of all imported drugs valued at $2,500 or less that it reviewed. FDA refuses approximately 1 percent of the drugs valued at $2,500 or less it examines at commercial ports and approximately 2 percent of the drugs valued at $2,500 or less it examines at couriers. Approximately 80 percent of the total drugs valued at $2,500 or less that FDA examines at IMFs were refused.

D. Effects of the Final Rule

Due to uncertainty about the method of destruction, how often the Agency will combine the notice and appeals process for destruction with refusal, and how often the Agency will destroy a refused drug valued at $2,500 or less, we must make certain assumptions in order to estimate the potential effects 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 we make in order to estimate the potential benefits and potential costs of the final rule that are presented in sections E and F of this document.

Assumptions:

(a) All refused drugs that are subject to destruction under the new authority will be destroyed.
(b) The costs associated with destroying a refused drug will be borne by FDA.
(c) Current and projected costs after refusal:
    i. Refused drug parcels at IMFs are currently exported at the expense of USPS. After adoption of the final rule all refused drug parcels valued at $2,500 or less will be destroyed at FDA's expense instead of being exported by USPS. This would represent a transfer of resources between the government agencies.
    ii. Refused drugs at express courier hubs are currently either exported or destroyed at the expense of the express courier. After adoption of the final rule all refused drug parcels valued at $2,500 or less will be destroyed at FDA's expense instead of being exported or destroyed by the express couriers. This could result in costs being shifted from the express couriers to FDA.

iii. Refused drugs at commercial ports are currently exported or destroyed at the expense of the importer because they take ownership of the drug. After adoption of the final rule, all refused drugs valued at $2,500 or less will be destroyed at FDA's expense instead of being exported or destroyed at the importer's expense. Since the value of a violative product is not appropriate to include in benefit-cost analysis, destruction of the violative drug would not result in a cost savings to importers but may add a cost to FDA.

(d) Destruction will be by incineration.
(e) The destruction of a refused drug valued at $2,500 or less will be contracted to another government agency or private firm.
(f) FDA will always combine the notice of destruction with the notice of refusal.
(g) 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 the assumptions and discuss the results in sections G and H.

E. Benefits of the Final Rule

Adopting the final rule will provide FDA with another enforcement tool to better protect the nation's drug supply chain. This new authority will allow FDA to destroy drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) offered for import once they have been refused admission into the United States. Primary benefits to society include the value of additional illnesses or deaths avoided by administrative destruction compared with other enforcement and regulatory actions that are currently available. If the violative drugs are substitutes for legitimate drugs, then the firms selling the legitimate drugs will receive benefits through increased sales. There will also be benefits from deterrence if administrative destruction increases the likelihood that violative drugs would not be imported in the future.

While the final rule will allow FDA to ensure a refused drug offered for import that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) is permanently removed from commerce in the United States through destruction, we are unable to estimate the total potential annual benefits because we cannot measure the effectiveness of current enforcement and regulatory actions. Also, it is difficult to get an accurate estimate of the prevalence of the illicit drug trade and the current impact on consumers, producers, and the economy due to the multiple dimensions that must be considered, including types of drugs, consumer substitution for drugs purchased on the internet, and the prevalence of counterfeit drugs (Ref. 9). 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 probability of an event occurring or the possible reduction in all costs of an event associated with each regulatory option. What follows is a qualitative discussion of the types of benefits that may be realized by consumers and producers with finalization of the final rule. We

end this section with a quantitative discussion of the possible cost savings to express couriers 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 drugs not approved in the United States. Drugs not approved for sale in the United States may not be safe or effective. Counterfeit drugs may contain no active ingredient, an incorrect active ingredient, which may or may not be toxic, or an incorrect amount of the active ingredient. For certain classes of drugs (e.g. antibiotics), quality problems can increase the likelihood of drug resistance. Consumers who take unsafe or ineffective drugs may die, become ill, or remain sick longer than they otherwise would have with safe and effective drugs. For examples of adverse events associated with unsafe, ineffective, and counterfeit drugs, see Section I of the proposed rule (79 FR 25758).

Consumers taking ineffective and unsafe drugs also waste financial resources on the violative drug with no benefit and may lose confidence in the healthcare industry. In addition to the direct consequences faced by the consumer of unsafe and ineffective drugs, 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 drugs would decrease the likelihood of illness, death, or the development of resistant strains of bacteria.

2. Possible Benefits to United States Pharmaceutical Producers

Imported, counterfeit versions of legitimate drugs may nonetheless be attractive to American consumers due to their often lower prices. The purchase of counterfeit drugs may result in four negative effects on the drug industry. First, when consumers substitute the counterfeit drug for the legitimate drug the producer of the legitimate drug sells fewer drugs, resulting in lower revenues. Second, firms must devote resources to defending their brand against counterfeiters with legal counsel, anti-counterfeit investigations, and anti-counterfeiting technologies. Third, consumers who unknowingly purchase an ineffective, unsafe, or counterfeit drug may lose confidence in the legitimate drug's manufacturer. Finally, the prevalence of counterfeit drugs may reduce a firm's desire to invest in the research and development of new drugs. Any reduction in the consumption of unapproved and counterfeit drugs may decrease these adverse effects on the drug industry.

3. Possible Transfer to Express Couriers

Currently, once a drug is refused entry at an express courier hub, the drug is either exported or destroyed within ninety days. We assume express couriers choose whether to export or destroy the refused drug and that they initially bear all the expenses. With adoption of the final rule, we assume that FDA, not the express couriers, will bear the cost of destruction. The estimated benefit of the final rule to express couriers includes the savings of having FDA assume the cost to destroy a refused drug as opposed to the costs express couriers currently bear to export or destroy the refused drug. If we assume all refused drugs will be destroyed, express

couriers will receive a net benefit equal to a cost savings of not having to destroy or export refused drugs. Over the last 4 fiscal years, an average of approximately 2,150 drug shipments has been refused at express courier hubs each year.

The cost of exporting a product once it has been refused entry into the United States includes the cost for use of physical and human resources. To estimate how much it costs to return a drug received at an express courier hub we reviewed international shipping costs for packages valued at $1 and $2,500 weighing 1 or 20 pounds from several express couriers for several international destinations. We estimate it costs, on average, between $20 and $345 to mail a package to an international destination via an express courier. Therefore, we estimate it will cost express couriers between $43,000 (= $20 per drug * 2,150 refused drugs) to $741,750 (= $345 per drug * 2,150 refused drugs).

Express couriers have the option to destroy refused products since they act as importers and take possession of the imported parcels. The cost associated with the destruction of the refused drug includes the cost for use of physical and human resources. We assume express couriers use a local contractor to destroy a refused drug by incineration. We estimate the contracted cost to destroy refused drugs is a flat rate of $500 per month per courier hub. There were approximately 29 different express courier hubs in the United States that received international parcels containing drugs over the last 4 years. Since a majority of the drug refusals valued at $2,500 or less at express courier hubs come through a minority of the hubs we do not expect each hub had refused drugs valued at $2,500 or less to destroy each month; instead, we estimate express couriers only destroyed refused drugs 75 months to 140 months of the possible 348 months (= 29 hubs * 12 months) per year. Therefore, we estimate the primary cost of destroying the refused drugs valued at $2,500 or less by contract at the express courier hubs is in the range of $37,500 (= 75 months * $500 per month) to $70,000 (= 140 months * $500 per month) annually.

We assume the express courier sent the refused drug to be destroyed to the contractor in truckloads. We estimate it costs, on average, between $25 and $100 per month to transport the refused drugs to a local contractor. We estimate the costs to be between $1,875 (= 75 months * $25 per month) to $14,000 (= 140 months * $100 per month) annually.

The total cost of destroying the refused drugs is the summation of the physical cost of destruction and the cost of transporting the drugs to the contractor for incineration. We estimate the total cost of destroying refused drugs to express couriers each year to range from $39,375 (=$37,500 for destruction + $1,875 for transportation) to $84,000 (= $70,000 for destruction + $14,000 for transportation).

If FDA destroys these refused drugs, express couriers will have their costs reduced between $39,375 and $741,750 annually. These potential cost savings are presented with potential costs of the proposed rule in Table 3. Lower estimates of the range are based on the rates of shipping and destruction costs for 1-pound packages valued at $1 using the lower estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year. The upper estimates are based on the rates of shipping and destruction costs for 20-pound

Table 3 – Summary of Costs Associated with Exporting and Destroying a Drug

	Commercial Port	Courier	IMF
Average Number Refused	3,000	2,150	9,950
Cost Per Exported Drug			
Lower Estimate	$0	$20	$10
Upper Estimate		$345	$60
Total Cost to Export			
Lower Estimate	$0	$43,000	$99,500
Upper Estimate		$741,750	$597,000
Total Cost to Destroy			
Lower Estimate	$97,125	$39,375	$56,700
Upper Estimate	$288,000	$84,000	$64,800

packages valued at $2,500 using the upper estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year.

F. Costs of the Final Rule

The final rule may result in increased costs to FDA that includes the additional cost of destroying the refused drug and one-time costs of updating internal information technology systems, revising Chapter 9 in FDA's Regulatory Procedures Manual and internal import operations guidelines, and training FDA staff. Our analysis assumes FDA will choose to destroy all unapproved, adulterated, or misbranded drugs valued at $2,500 or less that have been refused admission into the United States. Therefore, the numbers produced in this section represent an upper bound.

We analyze the cost of administrative destruction actions relative to the baseline of taking the actions FDA would have taken prior to having received authority to take administrative destruction actions. Therefore, only the costs that go beyond the costs of exporting a refused drug are relevant here. Other potential costs may be incurred by industry if FDA decides not to destroy a drug after a challenge by the owner or consignee and the drug is subsequently released. The costs presented in this section represent only the potential negative impacts of the final regulation according to the assumptions made in Section D. Costs as a result of relaxing these assumptions are presented in sections G and H.

1. Costs of Destroying a Refused Drug

The primary cost of the final rule will be the actual destruction of the refused drug once it has met the criteria mentioned earlier in this document. Because the destruction of the refused drug is not in addition to exporting the drug, in order to get an estimate of the additional cost of the final regulation we must take into account the difference between destroying and exporting a drug. Currently, drug parcels that are refused admission at IMFs are exported at the expense of USPS. For drugs that are refused admission at express courier hubs and at air, land, and sea ports of entry, the importer must export or destroy the drug within ninety days.

The cost of exporting a drug includes the cost for use of physical and human resources. To get an estimate of how much it costs to return a good received at an IMF, we reviewed international shipping costs for packages valued at $1 and $2,500 weighing 1 or 20 pounds from USPS for several international locations. We estimate it costs between $10 and $60 to mail a package to an international destination via USPS. Over the last 4 fiscal years, approximately 9,950 drug parcels (where the drug has a value of $2,500 or less) have been refused at IMFs on average. Having FDA destroy these refused drug parcels will save USPS between $99,500 (= $10 per exported package * 9,950 drug parcels) and $597,000 (= $60 per exported package * 9,950 drug parcels) annually.

We do not include the cost to export a drug from an air, land, or sea port. We consider cost savings to USPS and the couriers because, although they take possession of the package, they never take "ownership" in the sense of being responsible for the package contents or receiving benefits from the good itself. The importer at an air, land, or sea port, by contrast, has responsibility for the good itself because they take possession of the detained articles while the admissibility determination is pending.

No matter which port the violative product enters, the importer loses a product with zero value. The value of an illegal or violative product is not appropriate to include in benefit-cost analysis. At the non-courier, non-IMF ports, the importer makes the decision to receive the product and in essence vouches for it; any costs they then bear if it is a violative drug do not "count" because the product has no value. If, however, FDA takes charge of disposing of the product, FDA would bear the cost of destruction.

The cost associated with the destruction of a drug includes the cost for use of physical and human resources. We assume destruction will occur by incineration and destruction will be contracted out to another government agency or a private firm. We estimate the contracted cost to FDA to destroy refused drugs will be a flat rate of $500 per month per IMF, commercial port, and express courier hub. We estimated the total cost to destroy the refused drugs at the express courier hubs in Section E.3 to be between $39,375 and $84,000.

There are currently 9 IMFs in the United States. We assume FDA will have refused drugs valued at $2,500 or less to destroy at each IMF each month because of the large volume of refused drugs valued at $2,500 or less that attempt entry into the United States through IMFs. We estimate the primary cost of destroying the refused drugs at the IMFs by contract will be approximately $54,000 (= 9 IMFs * 12 months * $500 per month) annually.

There are approximately 134 different commercial ports in the United States that have received international parcels containing drugs over the last 4 years. Since a majority of the drug refusals valued at $2,500 or less at commercial ports come through a minority of the ports we do not expect FDA will have refused drugs valued at $2,500 or less to destroy at each port each month; instead, we estimate FDA will only destroy refused drugs at commercial ports 185 months to 480 months of the possible 1,608 months (= 134 hubs * 12 months) per year. Therefore, we estimate the primary cost of destroying the refused drugs by contract will be in the range of $92,500 (= 185 months * $500 per month) to $240,000 (= 480 months * $500 per month) annually.

We assume FDA will send the refused drug to be destroyed to the contractor in truckloads. We estimate it costs, on average, between $25 and $100 per month to transport the refused drugs to a local contractor. We estimated the total cost to transport the refused drugs at the express courier hubs in Section E.3 to be between $1,875 and $14,000. We estimate it will cost FDA between $2,700 (= 108 months * $25 per month) to $10,800 (= 108 months * $100 per month) annually at IMFs and between $4,625 (= 185 months * $25 per month) to $48,000 (= 480 months * $100 per month) annually at commercial ports.

The total annual cost to FDA of destroying the refused drugs valued at $2,500 or less will be the summation of the physical cost of destruction and the cost of transporting the drugs to the contractor for incineration. We estimate the annual cost to FDA of destroying refused drugs to be between $39,375 (= $37,500 for destruction + $1,875 for transportation) to $84,000 (= $70,000 for destruction + $14,000 for transportation) at the express courier hubs, between $56,700 (= $54,000 for destruction + $2,700 for transportation) to $64,800 (= $54,000 for destruction + $10,800 for transportation) at the IMFs, and between $97,125 (= $92,500 for destruction + $4,625 for transportation) to $288,000 (= $240,000 for destruction + $48,000 for transportation) at the commercial ports.

The total annual cost to FDA of destroying all refused drugs at all ports of entry into the United States is estimated to range between $193,200 (=$39,375 express courier hubs + $56,700 IMFs + $97,125 commercial ports) and $436,800 (= $84,000 express courier hubs + $64,800 IMFs + $288,000 commercial ports).

As we discussed earlier, the cost of this final rule will be the difference between the costs of destruction and the cost of exporting the refused drug. Therefore, we estimate the additional effect to the public sector for destroying refused drugs valued at $2,500 or less to be between a cost of $93,700 (= $193,200 cost to FDA to destroy each year - $99,500 cost to USPS to export each year) and a benefit of $160,200 (= $436,800 cost to FDA to destroy each year - $597,000 cost to USPS to export each year) per year. Table 3 presents the costs associated with exporting and destroying a drug at IMFs, express couriers, and air, land, and sea ports.

2. Costs to FDA of Updating OASIS

FDA expects it will need to update OASIS in order to handle the new notices and procedures for destruction. For example, fields will need to be created to identify refused drugs that are to be destroyed, track the custody of the refused drug from FDA to contractor, weight of the refused drug to be destroyed, and date the refused drug is destroyed. In addition, the format and language of the refusal notice will need to be updated to include the destruction notice. FDA approximates the one-time cost of updating OASIS to be $500,000. This is a one-time cost to the Agency and does not vary with the number of refused drugs.

3. Costs of Revising Import Operations Guidelines

Portions of several FDA and inter-Agency guidelines, including Chapter 9 in FDA's Regulatory Procedures Manual, relating to the importation of drugs will need to be revised as

result of the final rule. A majority of the revisions will take place using FDA resources. CBP and USPS may also allocate resources to the revisions of these guidelines.

We estimate the value of each FDA, CBP, and USPS representatives' time based on the hourly cost per full-time equivalent (FTE) employee for each Agency. FTE hourly rate used in this analysis are $120 for FDA, $95 for CBP, and $40 for USPS.

FDA estimates it will take a total of 150 FDA FTE hours, 26 CBP FTE hours, and 10 USPS FTE hours to revise all guidelines. The estimated cost to each Agency will be $18,000 (= $120 per hour * 125 hours) for FDA, $2,470 (=$95 per hour * 26 hours) for CBP, and $400 (=$40 per hour * 10 hours) for USPS. The estimated total costs for updating the import operations guidelines is $20,870 (= $18,000 FDA costs + $2,470 CBP costs + $400 USPS costs). This is a one-time cost to the Agencies and does not vary with the number of refused drugs.

4. Costs to FDA for Training Staff

FDA expects it will need to train 30 import branch staff members on the updates to OASIS and revisions to the import operations documents. The web-based training will last approximately 3 hours. At an FDA FTE hourly rate of $120 the total cost of the training will be approximately $10,800 (= 30 FDA employees * 3 hours * $120 per hour).

This additional 3 hours of training will be required in the first year for all current employees. Future training sessions will incorporate the new process. Therefore we consider this a one-time cost.

5. 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 drug associated with preparing for the administrative destruction action and the storage costs to FDA associated with holding the product before it is destroyed. We do not include the costs of preparing for the determination that a refused drug should be destroyed because we assume the FDA compliance officer will make the determination to pursue destruction at the same time as the determination to refuse the product, and the destruction notice and proceedings will be combined with the refusal notice and proceedings. We also do not anticipate a storage time between the determination to destroy and the destruction of the drug that is different from the storage time between the determination to refuse entry and the drug being shipped back to its address of origin. In short, we estimate that administrative destructions will not result in any additional regulatory or storage costs.

6. Summary of Total Net Costs

FDA estimates that implementing the final rule may result in an average annual effect in the range of a cost of $54,325 (= $93,700 public sector costs - $39,375 express courier benefits) to a cost savings of $901,950 (= $160,200 public sector costs - $741,750 express courier benefits). This range represents a best estimate given the information available and the

Table 4 – Summary of Net Costs of Destroying Refused Drugs

	Lower Estimate	Upper Estimate
Net Annual Costs	**$54,325**	**-$901,950**
Net One-Time Costs	**$531,670**	**$531,670**
Annualized Net Costs at 3% Discount Rate	**$89,021**	**-$867,254**
Annualized Net Costs at 7% Discount Rate	**$101,228**	**-$855,047**

assumptions made in Section D. In all cases, we base the low end of the range on the rates of shipping and destruction costs for 1-pound packages valued at $1 using the lower estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year. The upper end is based on the rates of shipping and destruction costs for 20-pound packages valued at $2,500 using the upper estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year.

In addition to the estimated annual costs and cost savings, FDA estimates the Agency will incur one-time costs totaling $531,670 (= $500,000 OASIS update + $20,870 guideline revisions + $10,800 FDA training) for the updating of FDA IT systems revising internal import operations guidelines, and training for FDA employees on the new process. This is a one-time cost and does not vary with the number of refused drugs.

A summary of the estimated quantifiable total net costs that may result with the implementation of the final rule based on the assumptions presented in Section D with their 20-year annualized values are presented in Table 4, where negative values represent a cost savings to society. Cost savings may accrue in cases where the cost of destroying the refused drug is less than the cost of returning the refused drug to its country of origin, which is the current procedure.

We base the lower estimate of the range on the rates of shipping and destruction costs for 1-pound packages valued at $1 using the lower estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year. The upper estimate is based on the rates of shipping and destruction costs for 20-pound packages valued at $2,500 using the upper estimate of expected truckloads of refused drugs being sent to a contractor for destruction each year. The net effect of the final rule annualized over 20 years is estimated to range from a cost of $89,021 to a benefit of $867,254 at a 3 percent discount rate and a cost of $101,228 to a benefit of $855,047 at a 7 percent discount rate.

In the following two sections, G and H, we relax our assumptions and present alternative scenarios with their associated costs in order to reflect all possible uses of this authority. Estimates presented in Section G should be interpreted as in lieu of the lower and upper estimates presented in Table 4. Estimates presented in Section H should be interpreted as in addition to the lower and upper estimates presented in Table 4.

Additional uncertainties are associated with these cost estimates, but are not reflected in the ranges reported in Table 4. Additional costs to FDA associated with notifying the owner or consignee of the refused drug, storing the refused drug, and preparing for challenges to destruction by owners or consignees are not included because we assume the process of notifying, storing, and providing the opportunity to appear and introduce testimony on the

Table 5 – Sensitivity Analysis: Net Costs of Destroying Refused Drugs

	Number of Drugs Destroyed	Lower Estimate	Upper Estimate
Destroy 25% of Refused Drugs	3,775		
Annualized at 3% Discount Rate		$48,277	-$190,792
Annualized at 7% Discount Rate		$60,484	-$178,585
Destroy 50% of Refused Drugs	7,550		
Annualized at 3% Discount Rate		$61,858	-$416,279
Annualized at 7% Discount Rate		$74,065	-$404,072
Destroy 75% of Refused Drugs	11,325		
Annualized at 3% Discount Rate		$75,439	-$641,767
Annualized at 7% Discount Rate		$87,646	-$629,560
Destroy Only Refused Drugs at IMFs	9,950		
Annualized at 3% Discount Rate		-$8,104	-$497,504
Annualized at 7% Discount Rate		$4,103	-$485,297

destruction of a drug will be combined with the process of notifying, storing, and providing the opportunity to appear and introduce testimony on the refusal of a drug. We address several of these uncertainties in the following two sections.

G. Sensitivity Analysis

It is possible that FDA may not destroy all drugs valued at $2,500 or less that are refused entry into the United States due to resource constraints or other considerations. Table 5 presents the 20-year annualized net costs of FDA choosing to destroy 25 percent, 50 percent, and 75 percent of refused drugs valued at $2,500 or less, and the 20-year annualized net costs of FDA choosing to perform its destruction authority at the IMFs only where we assume every drug parcel that is refused admission at an IMF will be destroyed. We assume the one-time costs discussed in sections F.2 – F.4 will remain the same for each scenario and have included these costs in Table 5. Negative values in Table 5 represent cost savings to society.

All quantifiable benefits and costs mentioned in sections E and F are included in the sensitivity estimates presented in Table 5; therefore, these benefits are to be considered in lieu of the lower and upper estimates presented in Table 4. We do not relax any of the other assumptions presented in Section D in these results. In all cases, we based the low end of the range on the rates of shipping and destruction costs for 1-pound packages valued at $1. Lower bounds of the estimates for destroying 25 percent, 50 percent, and 75 percent of destroyed drugs use the respective percentages of the lower estimates of expected truckloads of refused drugs being sent to a contractor for destruction each year. The upper end is based on the rates of shipping and destruction costs for 20-pound packages valued at $2,500. Upper bounds of the estimates for destroying 25 percent, 50 percent, and 75 percent of destroyed drugs use the respective percentages of the upper estimates of expected truckloads of refused drugs being sent to a contractor for destruction each year.

Table 6 – Summary of Costs of Operational Alternatives

	Lower Estimate	Upper Estimate
FDA Destroys Refused Drug:		
Annualized at 3% Discount Rate	$194,763	$1,796,172
Annualized at 7% Discount Rate	$195,911	$1,824,872
FDA Sends Separate Destruction Notices	$1,819,550	$1,827,100
Storage of Refused Drug	$1,210,000	$3,630,000

H. Operational Alternatives

In this section we present the net costs associated with relaxing the assumptions that destruction would be contracted out, FDA would always combine the notice of destruction with the notice of refusal, and FDA would always combine the opportunity to present testimony for destruction with the opportunity to present testimony for refusal. The net impacts of relaxing these assumptions are presented in Table 6. We continue to assume we will destroy all refused drugs; therefore, values in Table 6 can be thought of as costs in addition to the estimates presented in Table 4.

1. Net Effect of FDA Handling Destruction Regionally

It is possible FDA would not, for policy reasons, contract for the destruction of a refused drug valued at or below $2,500 with another government agency or private firm. If this is the case, FDA would be responsible for the purchase of the equipment needed to destroy the drug, training of staff to perform the destruction, and other costs related to the actual destruction of the refused drug, such as labor and fuel costs.

a. Purchase of Destruction Equipment

If FDA were to choose to destroy the refused drugs itself, the Agency anticipates purchasing at most 1 incinerator for each of its five import regions. We estimate that an incinerator that may be used to destroy a refused drug could cost between $10,000 and $250,000 depending on the size and features. Therefore, we estimate the cost to purchase the equipment needed to destroy refused drugs with a reported value of $2,500 or less to be between $50,000 (= 5 furnaces * $10,000 per furnace) and $1,250,000 (= 5 furnaces * $250,000 per furnace). This represents an initial cost and would not be an annual expense. It also represents the highest-cost destruction scenario.

b. Training in Destruction for FDA Staff

At least two FDA employees in each region may need to receive annual training in order to perform a proper destruction of a refused drug, with each training session being 4 hours long and administered by an FDA employee. We use the hourly FTE rate of $120 to estimate the cost of the training. If three employees (1 instructor and 2 attendees) participate in a 4-hour training session at each location each year, we estimate it could cost FDA approximately $7,200 (= $120 wage rate * 3 FDA employees * 4 hours of training * 5 training sessions) annually.

c. Costs Associated with Each Destruction Act

We estimate each furnace would be able to incinerate 30 – 50 pounds of drugs each hour. We approximate each refused drug valued at $2,500 or less to weigh between 1 and 20 pounds. Therefore, we estimate it would take between 2 and 40 minutes of work for one employee to destroy each refused drug. Therefore the estimated labor costs range between $4 (= 2 / 60 minutes * $120 per hour) and $80 (= 40 / 60 minutes * $120 per hour) per destroyed drug. This represents a total annual labor cost of $60,400 (= $4 labor cost per destroyed drug * 15,100 destructions) to $1,208,000 (= $80 labor cost per destroyed drug * 15,100 destructions) per year.

FDA would also incur fuel and other resource costs; we estimate that the resource-related costs would be between $16 and $32 for each act of destruction. This would add an additional $241,600 (= $16 in resource costs per destruction * 15,100 destructions) to $483,200 (= $32 in resource costs per destruction * 15,100 destructions) to annual costs.

We anticipate being able to send the drug to be destroyed via mail or express courier. We estimate it costs, on average, between $5 and $30 to mail a package domestically, depending on the size of the package and the distance to the incinerator. It is possible that some of the refused drugs will be destroyed at the facility where they were detained; however, we cannot predict the distribution of destroyed drugs around the United States. Therefore, we anticipate a maximum of 15,100 drugs would be mailed to an FDA destruction facility each year. We estimate the cost of mailing drugs to be destroyed to an FDA destruction facility to be between $75,500 (= $5 per package * 15,100 packages) and $453,000 (= $30 per package * 15,100 packages).

d. Total Net Effect of FDA Handling Destruction Regionally

Under this highest-cost scenario for destroying refused drugs valued at $2,500 or less, FDA would incur an upfront cost of $50,000 to $1.25 million for the purchase of the equipment. The annual costs of FDA not contracting out the destruction of the refused drugs would be the summation of all training, labor, other resource costs and the cost of mailing the drug to the incinerator. We estimate these annual costs to be between $384,700 (= $7,200 in training costs + $60,400 in labor costs + $241,600 in fuel and other costs + $75,500 for mailing) to $2,151,400 (= $7,200 in training costs + $1,208,000 in labor costs + $483,200 in fuel and other costs + $453,000 for mailing).

The net annual impact of FDA destroying all refused drugs valued at $2,500 or less annually is the difference between the annual costs presented in the above paragraph and the annual costs of destruction presented in Table 3. We estimate the additional annual costs of FDA performing its own destruction to range between $191,500 (= $384,700 FDA destroys refused drugs - $193,200 FDA cost of destruction contract) and $1,714,600 (= $2,150,400 FDA destroys refused drugs - $436,800 FDA cost of destruction contract). These values are in addition to the up-front purchase of destruction equipment. Annualized over 20 years, the additional cost of FDA handling the destruction of refused drugs regionally is estimated to range from $194,763 to $1,796,172 at a 3 percent discount rate and $195,911 to $1,824,872 at a 7 percent discount rate.

2. Net Effect of Not Combining Notices of Destruction with Notices of Refusal

According to the final rule, FDA would have the option to combine the notices of the intent to destroy and the Agency's destruction decision with the notices of the intent to refuse and the Agency's refusal decision for each detained drug valued at $2,500 or less. Our primary estimates assume these notices will be combined. Since there would be no additional cost to combining the notices, we did not include notification as a cost. However, FDA may choose not to combine the notices, and instead send a separate notice for intent to destroy and notification of destruction. Assuming this scenario, we anticipate FDA would incur labor and resource costs for each correspondence with the owner or consignee of a refused drug valued at or below $2,500 that FDA intends to destroy. Labor costs include the time needed for an FTE to create the notification and send the notice to the owner or consignee. We estimate it would take 0.5 hours of labor for each correspondence at an hourly FTE rate of $120. This gives us an estimate of $60 for labor costs for each notification. We assume the notices would not be sent electronically and resource costs, such as ink, paper, and envelopes, are estimated to be between $0.25 and $0.50 per notification.

We assume that FDA would send two notifications for each of the 15,100 possible destructions each year. This would result in FDA sending 30,200 notifications. At a labor cost of $60 per notification and a resource cost between $0.25 and $0.50 per notification, we estimate the total cost of not combining notices of destruction with notices of refusal to be between $1,819,550 (= [$60 labor cost per notification * 30,200 notifications] + [$0.25 resource cost per notification * 30,200 notifications]) and $1,827,100 (= [$60 labor cost per notification * 30,200 notifications] + [$0.50 resource cost per notification * 30,200 notifications]) annually.

3. Net Effect of Not Combining the Opportunity to Testify on Refusal and Destruction

According to the final rule, the notice of the intent to destroy will specify a time period during which the owner or consignee may challenge FDA's intent to destroy, either orally or in writing. Currently, an owner or consignee has the opportunity to appear and present testimony to FDA on 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 Agency will have already anticipated destruction if the drug is refused. However, if the opportunities to present testimony on refusal and destruction are not combined, for reasons including the FDA receiving additional information about the drug 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 drug 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 drug would take up space that could be used for other operations. We estimate the opportunity cost of the space needed to store each refused drug may be between $5 and $15. 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 decision to destroy. If a refused drug is held up 20 days, total storage costs for that drug may cost between $100 (= $5 per day * 20 days) and $300 (= $15 per day * 20 days).

When estimating the total possible storage costs subject to this final rule, we must consider who holds the refused drug during the period of time when the owner or consignee has the opportunity to introduce testimony. We assume that at the IMF, FDA will maintain possession; at the express courier hub, the express courier will maintain possession, and at the air, land and sea ports, the importer will maintain possession. We consider only the storage costs at the IMFs and the express courier hubs. Our analysis only considers storage costs to the importer at the other ports of entry in circumstances where FDA determines, after notice to the owner or consignee, that the drug may be released for entry into the United States.

FDA refuses approximately 12,100 drugs valued at $2,500 or less at the IMFs and express courier hubs annually. Multiplying by the total cost to store a drug for up to 20 days, we estimate the cost of not combining the opportunity to present testimony on refusals and destruction to range between $1,210,000 (= $100 cost to store each drug * 12,100 refused drugs) and $3,630,000 (= $300 cost to store each drug * 12,100 refused drugs) each year.

I. International Effects

The pharmaceutical industry is global, with manufacturing and consumption of a product often taking place in different parts of the world. The final rule will permit FDA to destroy drugs 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 exporting compliant drugs for distribution in the United States will not be affected by this final rule. The final rule will be unlikely to alter the current mix of foreign and domestic manufacturing for the affected products.

J. Distributional Effects

As mentioned earlier, there will be a distributional effect among government agencies as a result of the final rule. Currently, refused drug parcels at IMFs that can be exported are returned to USPS for export. USPS bears the burden of returning these drugs with no reimbursement from FDA. Refused drug parcels at IMFs that cannot be exported are sent to CBP for destruction. CBP bears the burden of destroying these drugs with no reimbursement from FDA. The final rule will likely eliminate a portion of USPS's export burden and CBP's destruction burden due to the refused drug being destroyed by FDA.

In addition, owners or consignees of destroyed drugs are liable for the costs of destroying and storing the drug prior to destruction. Funds charged to and received from the owners and consignees of the destroyed drug will act as a transfer to FDA for reimbursement related to the costs of destroying the drug.

III. Final Regulatory Flexibility 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 would lessen the economic effect of the rule on small entities. U.S. federal

government agencies will bear the costs of the final rule. Therefore we certify that this final rule will not have a significant economic impact on a substantial number of small 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

1. Hamburg, Margaret, "Food and Drugs: Can Safety Be Ensured In a Time of Increased Globalization?" Presented at the Council of Foreign Relations New York Symposium, January 31, 2011, available at http://www.fda.gov/NewsEvents/Speeches/ucm242326.htm.

2. LegitScript.com, "Threat Assessment and Enforcement," available at http://www.legitscript.com/services/enforcement.

3. United States Food and Drug Administration, "BeSafeRx: Know Your Online Pharmacy Survey Highlights," available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/BuyingMedicinesOvertheInternet/BeSafeRxKnowYourOnlinePharmacy/ucm318497.htm.

4. National Association of Boards of Pharmacy, "Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators, October 2011," available at http://www.nabp.net/programs/assets/IDOI_Report_10-11.pdf.

5. Besson, Candice, "Thirty-Six Million Americans Have Bought Medications Online Without a Doctor's Prescription," The Partnership at Drugfree.org, December 14, 2010, available at http://www.drugfree.org/newsroom/thirty-six-million-americans-have-bought-medications-online-without-a-doctor%E2%80%99s-prescription-2.

6. Krebs, Brian, "Americans Use Spam for Cheaper Prescription Drugs," MIT Technology Review, July 11, 2011, available at http://www.technologyreview.com/news/424646/americans-use-spam-for-cheaper-prescription-drugs/.

7. United States Government Accountability Office, "Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods," April 2010, available at http://www.gao.gov/assets/310/303057.pdf.

8. World Health Organization, "Medicines: Spurious/Falsely-Labeled/Falsified/Counterfeit (SFFC) Medicines, Fact Sheet Number 275," May 2012, available at http://www.who.int/mediacentre/factsheets/fs275/en/.

9. National Intellectual Property Rights Coordination Center, "Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad," November 2011, available at http://www.iprcenter.gov/reports/ipr-center-reports/IPR%20Center%20Threat%20Report%20and%20Survey.pdf/view.