executing the RNAV (GPS) RWY 27 approach.

In addition, the existing Class E airspace extending upward from 1,200 feet above the surface is removed, as the area is already within the Coaldale Class E en route domestic airspace area.

Finally, the FAA is modifying the airport's legal descriptions. The airport name within the text headers of both airspace legal descriptions, and any reference within the bodies, are changed to match the new airport name, Mammoth Yosemite Airport (formerly Mammoth Lakes Airport). The geographic coordinates located in the text header of both airspace legal descriptions are updated to match the FAA's database.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AWP CA E2 Mammoth Lakes, CA [Amended]

Mammoth Yosemite Airport, CA
(Lat. 37°37′27″ N, long. 118°50′20″ W)

That airspace within a 4.1-mile radius of Mammoth Yosemite Airport and within 1 mile either side of the airport's 096° bearing extending from the 4.1-mile radius to 4.6 miles east of the airport.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AWP CA E5 Mammoth Lakes, CA [Amended]

Mammoth Yosemite Airport, CA
(Lat. 37°37′27″ N, long. 118°50′20″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Mammoth Yosemite Airport and within 2.6 miles either side of the airport's 091° bearing, extending from the 6.6-mile radius to 13.1 miles east.

* * * * *

Issued in Des Moines, Washington, on May 24, 2024.

Paul J Higgins,

Group Manager (A), Operations Support Group, Western Service Center.

[FR Doc. 2024–11894 Filed 5–30–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2021–N–1348]

RIN 0910–AI59

Administrative Destruction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a regulation to implement our 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 by providing to the owner or consignee notice and an opportunity to appear and introduce testimony prior to the destruction. We are finalizing the change to our internal procedures for administrative destruction of drugs and devices. The notice of proposed rule making (NPRM) published in the **Federal Register** (October 7, 2022).

DATES: This rule is effective July 1, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4375, Silver Spring, MD 20993–0002, 301–796–3324.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The final rule provides to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively 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. The Safeguarding Therapeutics Act (STA) (Pub. L. 116–304), signed into law on January 5, 2021, amended section 801(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(a)) to provide FDA with the authority to administratively destroy certain refused devices without providing the owner or consignee with the opportunity for export. FDA is amending § 1.94 (21 CFR 1.94) to provide to the owner or consignee of a refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to present testimony to the Agency prior to destruction of the device.

B. Summary of the Major Provisions of the Final Rule

The final rule provides to an owner or consignee notice and an opportunity to present testimony when the Agency intends to administratively 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 section 801(a) of the FD&C Act.

FDA is amending part 1 (21 CFR part 1) by expanding the scope of § 1.94, which provides to the owner or consignee notice and opportunity to present testimony prior to the refusal and destruction of certain refused drugs, to also include notice and opportunity to present testimony prior to the refusal and destruction of certain refused devices.

C. Legal Authority

We are issuing this final rule under sections 701 and 801 of the FD&C Act (21 U.S.C. 371 and 381, respectively).

D. Costs and Benefits

The primary public health benefit of the final rule will be the value of preventing additional illnesses or deaths by destroying, rather than returning, refused devices valued at $2,500 or less, which may pose a public health risk. This benefit will accrue whenever FDA's existing enforcement tools would not have prevented the violative device from entering the U.S. 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.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/acronym	What it means
Agency	U.S. Food and Drug Administration.
CBP	U.S. Customs and Border Protection.
COVID–19	Disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2).
FDA	U.S. Food and Drug Administration.
FDASIA	Food and Drug Administration Safety and Innovation Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
IMFs	International Mail Facilities.
IOM	Investigations Operations Manual.
NPRM	Notice of Proposed Rule Making.
OASIS	FDA's Operational and Administrative System for Import Support.
RPM	Regulatory Procedures Manual.
SERIO	FDA's System for Entry Review and Import Operations.
STA	Safeguarding Therapeutics Act.
TBT Agreement	Technical Barriers to Trade Agreement.
USPS	U.S. Postal Service.
We, Our, Us	U.S. Food and Drug Administration.

III. Background

A. Need for the Regulation/History of This Rulemaking

Section 708 in the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), enacted in 2012, gave FDA the authority in section 801(a) of the FD&C Act to destroy, without providing an opportunity for export, any refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). Section 801(a) of the FD&C Act, as amended by FDASIA, allows the Agency to combine the notice and opportunity to introduce testimony on the admissibility of the drug under section 801(a) of the FD&C Act with the notice and opportunity to introduce testimony on the destruction of the drug, as long as appropriate notice is provided to the owner or consignee.

To implement that authority, FDA published a final rule in the **Federal Register** on September 15, 2015 (80 FR 55237) that revised § 1.94 to provide notice and an opportunity for the owner

or consignee to appear before the Agency and introduce testimony prior to the destruction of a drug.

The STA expanded FDA's administrative destruction authority to include any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). To implement this authority, we issued a proposed rule to amend § 1.94 to provide to the owner or consignee of any refused device valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) notice and an opportunity to appear and introduce testimony prior to the destruction. An NPRM was published in the **Federal Register** on October 7, 2022 (87 FR 60947).

As discussed in the preamble to the proposed rule, FDA has refused devices, including those valued at $2,500 or less, sent to the United States via international mail or express couriers, including illegal devices that are being imported to diagnose, prevent, or treat COVID–19 such as test kits, respirators, and face masks. Examples of other devices that pose significant public health concerns if counterfeit, unapproved, or unauthorized, or otherwise misbranded or adulterated, include contact lenses and blood glucose test strips.

There is currently little deterrence against sellers shipping illegal devices or re-sending previously refused devices to the United States via international mail or an express courier. Devices that have been refused admission into the United States might be subsequently offered for re-importation by unscrupulous sellers who attempt to circumvent U.S. import regulatory systems. Under the final rule, FDA will be better able to deter such shipments by having an administrative mechanism for destroying 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.

For further information on the need for this regulation, see section III.B. (Need for the Regulation) of the NPRM (87 FR 60947 at 60949–60951). The need for this regulation as discussed in the preamble to the proposed rule applies to the final rule.

B. Summary of Comments to the Proposed Rule

We received approximately 10 comment letters on the proposed rule by the close of the 60-day public comment period, each containing 1 or more comments on 1 or more issues. We received comments from individuals, an association, a business, medical personnel, and a foreign government. Some comments were submitted anonymously. The majority of the comments supported the proposed rule.

IV. Legal Authority

FDA has the legal authority under section 801(a) of the FD&C Act, as amended by the STA, to administratively destroy, without providing opportunity for export, any 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. A device that is imported or offered for import is subject to refusal of admission under section 801(a) of the FD&C Act if, among other reasons, it appears to be adulterated or misbranded in violation of section 501 or 502 of the FD&C Act (21 U.S.C. 351 or 352).

Section 801(a) of the FD&C Act directs FDA to issue regulations that provide the owner or consignee of a device designated by the Agency for administrative destruction with notice and an opportunity to introduce testimony to us prior to the destruction of the device. Section 801(a) of the FD&C Act further states that this process may be combined with the notice and opportunity to appear before FDA and introduce testimony on the admissibility of the device under section 801(a) of the FD&C Act, as long as appropriate notice is provided to the owner or consignee.

Additionally, section 701(a) of the FD&C Act authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

As used throughout, the term ''device'' means those articles meeting the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), which includes devices intended for human or animal use. Section 201(h) of the FD&C Act defines the term ''device,'' in part, as 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 of man or other animals or by being metabolized.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We describe and respond to the comments received in the public docket in sections V.B., V.C., and VI of this document. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's importance or the order in which comments were received.

The Agency also received a number of comments that were not responsive to the content of the proposed rule and therefore were not considered in its final development.

After considering the comments responsive to the proposed rule, the Agency is not making any changes to the text of the regulation included in the proposed rule.

B. Summary of General Comments to the Proposed Rule

Several commenters made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments.

(Comment 1) Some commenters recommended that FDA consider granting greater reciprocity for foreign manufactured diagnostic devices rather than expand administrative destruction because the Agency had not documented those products' adverse effects and suggested that the Agency should assume that the product is suitable for the U.S. market if cleared by a foreign regulatory agency. One commenter recommended that FDA should return products cleared by a foreign regulatory agency so that they can be used in that foreign country.

(Response 1) We decline to follow the suggestion that FDA rely on the findings of a foreign regulatory agency rather than effectuate the authority granted to FDA by Congress in the STA. Section 801(a) of the FD&C Act, as amended by the STA, authorizes FDA to administratively destroy certain devices that are refused admission into the United States, and directs FDA to issue regulations that provide the owner or consignee of a device designated by the Agency for administrative destruction

with notice and an opportunity to introduce testimony to us prior to the destruction of the device. The devices subject to administrative destruction are governed by the FD&C Act and its implementing regulations to protect public health. FDA generally plans to take risk and other factors into account in determining whether to seek destruction of a particular device. In addition, we disagree with the suggestion to return devices that meet the criteria for administrative destruction to the country where they have been ''cleared'' as this may be difficult due to an exporter not being located in that country and any such return could result in those products being reimported to the United States.

(Comment 2) Some commenters asserted that device manufacturers are more compliant than drug manufacturers so there is no need to expand administrative destruction to devices. Other commenters noted the influx of ''faulty'' and ''fake'' devices such as COVID–19 tests, respirators, face masks, and other personal protective equipment during the COVID–19 pandemic.

(Response 2) By passing the STA, Congress determined that expanding administrative destruction to devices was appropriate. Additionally, in the preamble to the proposed rule, we discussed numerous examples of illegal devices that were imported or offered for import, the public health risk associated with such illegal devices, and the lack of deterrence without administrative destruction (87 FR 60947 at 60949–60951). As discussed above and in the preamble to the proposed rule, we believe administrative destruction of illegal devices that are imported or offered for import is appropriate.

C. Specific Comments and FDA Response

(Comment 3) One commenter expressed concern that the proposed rule states that section 801(a) of the FD&C Act would apply to ''certain devices'' without clarification as to the identity of those devices and another commenter asked what the selection process is for administrative destruction of devices under the rule.

(Response 3) As stated in the preamble to the proposed rule, the term ''device'' means those articles meeting the definition of device in section 201(h) of the FD&C Act, which includes devices intended for human or animal use (87 FR 60947 at 60951). When we use the term ''certain devices'', we mean those devices that meet the criteria for administrative destruction as provided in section 801(a) of the FD&C Act: a device that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that is refused admission into the United States (*e.g.,* because it appears to be adulterated or misbranded) and is not brought into compliance as described under section 801(b) of the FD&C Act.

Any device that is reviewed by FDA for admissibility and meets the criteria for administrative destruction may initially be selected for destruction. FDA staff will then determine, taking into account any applicable policies and the circumstances regarding the device and importation, whether to seek destruction. If the decision is made to select the device for destruction, FDA will give notice to the owner or consignee of FDA's intent to refuse and destroy the device.

(Comment 4) One comment asked whether the owner or consignee would have the option of having the shipment returned to its origin rather than destroyed as part of the notice and opportunity to offer testimony process.

(Response 4) An owner or consignee has an opportunity to contest the destruction of a device by providing testimony at an informal hearing before the Agency. FDA, not the owner or consignee, makes the determination whether a refused device will be returned or destroyed.

(Comment 5) One comment suggested that the Agency should include ''the testimony opportunity for the company providing product subject to this policy'' in the final rule.

(Response 5) We decline to require that the notice and opportunity for a hearing under § 1.94 be given to the company that provided the device. Section 801(a) requires that FDA provide to the owner or consignee of a device notice and an opportunity to provide testimony prior to the administrative destruction. Owner or consignee is defined in 21 CFR 1.83. As discussed in the preamble to the proposed rule, if the article was sent by international mail, FDA generally considers the addressee of that package to be the owner or consignee (87 FR 60947 at 60951). Consistent with section 801(a) of the FD&C Act and the process for administrative destruction of certain drugs under § 1.94, FDA believes that providing the owner or consignee of a device notice and an opportunity to provide testimony prior to administrative destruction is sufficient. The owner or consignee can choose to present testimony from the company providing the product (assuming the owner or consignee is not the company providing the product) if the owner or consignee decides to contest the destruction at an informal hearing before the Agency.

(Comment 6) One comment asked if there is a way for the public to be informed of the devices that are destroyed by FDA so that consumers can get rid of the item if it's in their possession.

(Response 6) We decline to provide such notice in this rule. As discussed in our response to comment 5, the notice required in section 801(a) of the FD&C Act and § 1.94 is for the purpose of allowing the owner or consignee of the device to contest the administrative destruction.

FDA currently provides on its website public notice of safety issues associated with devices through various means, *e.g.,* information about device recalls, consumer alerts or updates, news releases, and safety communications. We referenced some of these public notices for coronavirus tests, vaccines, and treatments, and contact lenses and glucose test strips in the preamble to the proposed rule (87 FR 60947 at 60954–60955). FDA also provides information about import alerts on its website to inform the Agency's field staff and the public that the Agency has enough evidence to allow for detention without physical examination of FDA-regulated products that appear to be in violation of FDA's laws and regulations.

To provide the necessary information for consumers to take action on destroyed devices, FDA would have to expend a significant amount of our limited resources to identify and publish the name of each destroyed device, its manufacturer, batch and lot number, and expiration date. We do not believe that such a large expenditure of FDA resources to provide that additional information to the public is warranted.

(Comment 7) A foreign government submitted a comment requesting that FDA clarify whether ''a device'' is regarded as a single item or a whole batch of devices of the same device category for the purpose of applying the $2,500 or less valuation for administrative destruction. The commenter also requested that the Agency provide a transition period for their device industry in accordance with Article 2.12 of the World Trade Organization Technical Barriers to Trade Agreement (TBT Agreement), stating that the rule will have a profound impact on the manufacturers or owners in their country.

(Response 7) Section 801(a) of the FD&C Act states that FDA may destroy ''any drug or device refused admission under [section 801 of the FD&C Act], if

such drug or device is valued at an amount that is $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation . . .)'' and requires the Agency to issue regulations providing notice and an opportunity to present testimony ''on destruction of a drug or device.'' FDA interprets this administrative destruction provision to apply the $2,500 or less valuation to a singular device rather than to an entire entry or shipment containing multiple devices of the same type or product code.

We decline to provide an additional transition period beyond that required by the Administrative Procedure Act. Because this rule does not meet the definition of a ''technical regulation'' of the TBT Agreement, as defined in Annex 1 of the Agreement, Article 2.12 of the TBT Agreement does not apply.

Additionally, we do not think an additional transition period is necessary, particularly since there is nothing for manufacturers to implement under this rule. This rule addresses certain illegal devices that are imported or being offered for import to the United States and implements the authority under the FD&C Act, as amended by the STA, for FDA to administratively destroy these devices rather than returning them.

As noted earlier, the STA was signed into law on January 5, 2021, over 3 years ago. The proposed rule was published well over a year ago, on October 7, 2022, and a 60-day period for submission of public comment followed. The final rule will be effective 30 days from publication in the **Federal Register**.

VI. Comments on FDA Procedures for Administrative Destruction and FDA Response

In the NPRM preamble, FDA explained that the Agency intends to make a change to the procedures for destroying a refused drug and intends to use the same procedures for devices that are subject to administrative destruction. Under our revised procedures for destruction, FDA might not make a determination that a drug or device subject to administrative destruction is, in fact, in violation of the FD&C Act if the owner or consignee has not requested a hearing to contest the administrative destruction (including the basis for refusal of admission). We will continue to make a determination that a drug or device is, in fact, in violation of the FD&C Act when an owner or consignee timely requests a hearing to contest the administrative destruction (including the basis for refusal of admission) (87 FR 60947 at 60951–60952).

The majority of the comments on the notice regarding the change to our internal administrative destruction procedures were supportive. FDA is finalizing the procedures described in the preamble in the NPRM published on October 7, 2022 (87 FR 60947 at 60951–60952) and will implement the procedures at the same time the final rule takes effect.

(Comment 8) One comment stated that there should be data made available for the counterfeit devices that are the subject of this rule rather than using the 99 percent rate for drugs that are designated for destruction and found to be adulterated or misbranded. Another commenter suggested that we sunset the program to evaluate, sometime after implementation, to see whether the 99 percent rate is substantially the same for devices that are subject to destruction. A different commenter requested that we make a report on the effectiveness of the program publicly available.

(Response 8) We used the data we have from the administrative destruction of drugs program that was implemented in April 2016 because we do not have data on the devices subject to administrative destruction given that the program for devices has not yet been implemented. FDA intends to periodically evaluate the effectiveness of its program and does not see a need to sunset the program while we perform an evaluation. Finally, at this time, we do not agree that public reports on the effectiveness of the program are warranted or would be an optimal use of FDA's limited resources.

VII. Effective Date

The rule is effective 30 days after publication of a final rule in the **Federal Register**.

VIII. Economic Analysis of Impacts

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 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 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 IMFs and express couriers. We do not, therefore, consider impacts related to shipments via commercial air, land, and seaports.[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.

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 (years)	
Benefits:							
Annualized Monetized ($m/y) [1]	$0.317	$0.148	$0.750	2022	7	10	Benefits include cost savings to express couriers and USPS.
	0.317	0.148	0.750	2022	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized ($m/y) [1]	0.475	0.068	1.586	2022	7	10	
	0.470	0.063	1.582	2022	3	10	
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 $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation).						
Transfers:							
Federal Annualized Monetized ($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.

[1] 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.

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 U.S. market; the current policy for returning refused devices does not preclude the re-importation of

[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.

the device into the United States in the future. We do not have enough information to quantify these benefits.

The destruction of refused devices will lessen the costs incurred to export and return refused devices to the country of origin (the current procedure for refused devices valued at $2,500 or less). Express couriers and the U.S. 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. FDA will additionally incur one-time costs to update its electronic OASIS and SERIO; revise its RPM, 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 notify separately the owners or consignees of refused devices, and costs to prepare for hearings on destruction that the owners or consignees of refused devices request. We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this rule (Ref. 1) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria*.

IX. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XII. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have Tribal implications as defined in the Executive order and, consequently, a Tribal summary impact statement is not required.

XIII. Reference

The following reference is on display with the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it also available electronically at *https://www.regulations.gov*. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA. Administrative Destruction: Regulatory Impacts Analysis, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2023. *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting, and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the Food and Drug Administration amends 21 CFR part 1 as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342, 343, 350c, 350d, 350j, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 374, 381, 382, 384a, 387, 387a, 387c, 393, and 2223; 42 U.S.C. 216, 241, 243, 262, 264, 271.

■ 2. In § 1.94, revise paragraphs (a) and (c) to read as follows:

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

* * * * *

(c) If the article is a drug or device that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

Dated: May 17, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

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DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Parts 550, 556, and 590

[Docket No. BOEM–2023–0027]

RIN 1010–AE14

Risk Management and Financial Assurance for OCS Lease and Grant Obligations; Correction

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final rule; correction.