4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2014-N-0504]

RIN 0910-AH12

Administrative Destruction of Certain Drugs Refused Admission to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is implementing its authority to destroy a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that has been refused admission into the United States under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), by issuing a rule that provides to the owner or consignee notice and an opportunity to appear and introduce testimony to the Agency prior to destruction. This regulation is authorized by amendments made to the FD&C Act by the Food and Drug Administration Safety and Innovation Act (FDASIA). Implementation of this authority will allow FDA to better protect the public health by providing an administrative process for the destruction of certain refused drugs, thus increasing the integrity of the drug supply chain.

DATES: This rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Ann M. Metayer, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4338, Silver Spring, MD 20993-0002, 301-796-3324, FDASIAImplementationORA@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Regulatory Action

Implementation of FDA's administrative destruction authority will better protect the integrity of the drug supply chain by providing a disincentive for the importation of drugs that are adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act (21 U.S.C. 355) (unapproved drugs) and reducing the likelihood of such drugs being refused admission and subsequently offered for reimportation. In 2012, Congress amended section 801(a) of the FD&C Act (21 U.S.C. 381(a)) to provide FDA with the authority to destroy a refused drug 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 with the opportunity to export the drug. Congress directed FDA to issue regulations that provide the drug's owner or consignee with notice and an opportunity to present testimony to the Agency prior to the drug's destruction (section 708 of FDASIA). The final rule provides the owner or consignee of a drug that has been refused admission into the United States, and that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

FDA is issuing this final rule under section 801(a) of the FD&C Act.

Summary of the Major Provisions

The final rule implements the authority of FDA to destroy a drug after providing the owner or consignee of a drug that has been refused admission into the United States under section 801(a) of the FD&C Act, and that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

FDA is amending part 1 (21 CFR part 1) by expanding the scope of § 1.94 (21 CFR 1.94) to include administrative destruction. Currently this provision provides the owner or consignee of an FDA-regulated product offered for import into the United States with notice and opportunity to present testimony to the Agency prior to refusal of admission of the product. The final rule expands the scope of § 1.94 to also provide an owner or consignee with notice and opportunity to present testimony to the Agency prior to the destruction of certain refused drugs.

Section 708 of FDASIA and the final rule allow FDA to provide two separate notices and hearings--one for refusal of admission and one for destruction of a refused drug product--or to combine both notices and hearings into one notice and proceeding. Whether the determinations occur separately or in one combined proceeding, the determination of refusal and the determination regarding destruction of a drug will be made separately by the Agency as the findings are separate and distinct.

Costs and Benefits

The primary public health benefit from adoption of the rule would be the value of the illnesses and deaths avoided because FDA destroyed a 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. This benefit accrues whenever the Agency's other enforcement tools would not have prevented a drug, including a biological product, which does not comply with the requirements of the FD&C Act (violative drug) from entering the U.S. market. The estimated primary costs of the final rule include the additional costs to destroy a violative drug and the one-time costs of updating the FDA Operational and Administrative System for Import Support (OASIS), making appropriate revisions to Chapter 9 of the FDA Regulatory Procedures Manual (RPM) and the Agency's internal import operations guidelines, and training for FDA personnel. FDA estimates the quantifiable net annual effect of the final rule to range between a cost of $54,325 and a cost savings of $901,950 for an estimated 15,100 destructions each year. The Agency estimates that it will also incur one-time costs of $531,670.

I. Background and Legal Authority

In the Federal Register of May 6, 2014 (79 FR 25758), FDA proposed a rule to implement its new authority under section 708 of FDASIA to destroy a refused drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation). As discussed in the preamble to the proposed rule, President Obama signed FDASIA (Pub. L. 112-144) into law on July 9, 2012. Title VII of FDASIA provides FDA with important new authorities to help the Agency better protect the integrity of the drug supply chain. One of those new authorities is provided in section 708 of FDASIA, which amends section 801(a) of the FD&C Act, to provide FDA with the authority to use an administrative procedure to destroy a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that was not brought into compliance as described in section 801(b) of the FD&C Act and was refused admission into the United States. Section 708 of FDASIA authorizes FDA to use this new administrative procedure without offering the owner or consignee the opportunity to

export the drug. The statute further provides that FDA will store and, as applicable, dispose of the drug that the Agency intends to destroy. The drug's owner or consignee is liable for FDA's storage and disposal costs under section 801(c) of the FD&C Act.

Section 708 of FDASIA directs FDA to issue regulations that provide the owner or consignee of a drug designated by the Agency for administrative destruction with notice and an opportunity to introduce testimony to the Agency prior to the destruction of the drug. The provision 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 drug under section 801(a) of the FD&C Act, as long as appropriate notice is provided to the owner or consignee.

II. Overview of the Final Rule Including Changes to the Proposed Rule

FDA is amending part 1 to implement the administrative destruction of refused drugs. The amendment to part 1 consists of amendments to § 1.94, including two technical changes to § 1.94(b) where "his" is now changed to "his or her" and "act" is now changed to "Federal Food, Drug, and Cosmetic Act" in the final rule. No changes have been made to the proposed regulation and, therefore, FDA is finalizing the implementing regulation as proposed.

III. Comments on the Proposed Rule

FDA received 22 comments in the public docket for the May 6, 2014, proposed rule by the close of the comment period, July 7, 2014, each containing one or more comments. One comment was received in the public docket on July 8, 2014, 1 day after the docket closed. These comments were submitted by consumers, consumer advocacy groups, industry and trade organizations, industry, and a member of Congress. One comment consisted of a "placeholder" and did not contain any substantive remarks.

After considering the comments responsive to the proposed rule, the Agency is not making any changes to the regulatory language included in the proposed rule.

This section contains summaries of the relevant portions of the responsive comments and the Agency's responses to those comments. To make it easier to identify the comments and our responses, the word "Comment," in parentheses, appears before the comment's description, and the word "Response," in parentheses, appears before our response. We have numbered each comment and response to help distinguish between different types of comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

The Agency also received some general comments that were not responsive to the content of the rule, and therefore were not considered in its final development. Some of these comments, however, are summarized in this section and the Agency responded to those comments to provide clarity for the public and industry on the Agency's implementation of its administrative destruction authority under section 708 of FDASIA.

A. Notice and Hearing Process

Two comments suggested that FDA modify the notice and hearing process in the proposed rule.

(Comment 1) One comment asserted that the procedure set forth in § 1.94 appears to apply only to large commercial drug imports, not drugs offered for import by individuals, and that FDA should create a separate administrative hearing process for individuals.

(Response 1) The proposed rule amends § 1.94 to add administrative destruction of certain drugs to the current administrative hearing process for refusal of admission of an FDA-

regulated product. The current rule applies to all imports regardless of how they enter the United States, e.g., via a commercial port or an International Mail Facility (IMF), and regardless of who seeks to import the drug. As amended by this final rule, § 1.94 will provide an administrative hearing process to any owner or consignee of a refused drug with a value of $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) that FDA intends to destroy whether that owner or consignee is an individual owner or consignee or a commercial importer. There is, therefore, no need to establish a separate administrative hearing process for individuals whose drugs have been refused and designated for administrative destruction.

(Comment 2) One comment stated that FDA should provide clarity for consumers regarding how they can introduce testimony to the Agency to challenge the administrative destruction of drugs they attempted to import but which were refused admission. The comment suggested that FDA allow testimony to be submitted by an affected owner or consignee through an online platform, email, regular mail, or facsimile and that the Agency include a supplemental document in the notice that instructs consumers on how to provide testimony to FDA to prevent administrative destruction of their drugs.

(Response 2) As described in Chapter 9 of the RPM, the type of administrative hearing under § 1.94 may vary from a series of telephone conversations to a more formal procedure. Introduction of testimony by the owner or consignee for Agency review and consideration can take many forms, including a telephone conversation, a facsimile, or mail, and does not have to be introduced in person. However, an in-person hearing will be scheduled if requested by the owner or consignee. (http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf). Current Agency procedures also allow such testimony to be submitted by the

owner or consignee by email. Under the final rule, owners or consignees will have the same options for submitting testimony in opposition to the destruction of their drugs. Given the variety of options historically available to owners and consignees for submission of testimony, which will continue under the final rule, FDA does not believe that a dedicated online platform for submission of testimony is currently needed. If circumstances change in the future, FDA will consider whether such a system is appropriate.

FDA recognizes that an owner or consignee importing a drug for his/her own personal use may need information about the administrative hearing process when that drug has been detained by FDA for administrative destruction. Accordingly, the Agency will provide information on the administrative hearing process under § 1.94, as amended in this rule, by providing an insert in the Agency's notice of detention or by establishing a Web page on the FDA Web site containing information about the administrative destruction process including ways to submit testimony to the Agency in opposition to the destruction of a drug. FDA will also consider issuing guidance or other explanatory materials, as appropriate.

B. Drugs Subject to Administrative Destruction by FDA

Two comments requested clarity regarding what drugs will be destroyed by FDA under section 708 of FDASIA.

(Comment 3) Two commenters requested clarity on when a refused drug will be destroyed under section 708 of FDASIA and when the Agency will give the owner or consignee the option to destroy or export a refused drug.

(Response 3) Currently, owners or consignees of drugs that have been refused admission into the United States under section 801(a) of the FD&C Act have the option to destroy or export those drugs. Drugs imported via an IMF that have been refused admission are sent back to the

United States Postal Service (USPS) for export. After implementation of section 708 of FDASIA, FDA anticipates that owners or consignees will still have the option to destroy or export a refused drug in at least two situations. First, only a drug valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) is subject to administrative destruction under section 708 of FDASIA. Owners or consignees of a drug valued over the current $2,500 threshold that has been refused admission will still have the option to destroy or export that drug unless the drug has been imported via an IMF. For a drug 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, section 708 of FDASIA allows FDA to destroy the drug without providing the owner or consignee with the opportunity to destroy or export the drug.

The second situation where owners or consignees will still have the option to destroy or export a refused drug is when FDA refuses admission to a drug, including a biological product, that is subject to destruction under section 708 of FDASIA, but the Agency is not able to make a determination that the drug is, in fact, adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. As stated in the proposed rule, FDA intends to administratively destroy a drug only where the Agency has made a determination that the drug is adulterated, misbranded, or is an unapproved drug. There may be situations where the Agency refuses admission to a drug that is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) because it appears to be an adulterated, misbranded, or unapproved drug but the Agency does not have sufficient information to make a determination that the drug is, in fact, an adulterated, misbranded, or unapproved drug. Under those circumstances, the owner or consignee will be given the opportunity to destroy or export that

refused drug. If such a drug has come into the United States via an IMF, however, FDA will generally return the drug to the USPS for export.

C. Storage and Destruction Costs of Drugs Designated for Destruction

Section 708 of FDASIA provides that FDA will store and, as applicable, dispose of a drug where the Agency has made the determination to destroy that drug. The drug's owner or consignee is liable for FDA's storage and disposal costs under section 801(c) of the FD&C Act.

(Comment 4) One comment asked when FDA will take physical possession of drugs designated for destruction at express courier facilities and expressed concern about the possibility of extended storage time for these drugs at the expense of the express courier. The commenter also requested clarification regarding whether an express courier could be held liable for the costs of storage and destruction of a refused drug under section 801(c) of the FD&C Act.

(Response 4) If FDA designates a drug for possible destruction that has been offered for import into the United States via an express courier, FDA intends to take physical possession of that drug when the Agency has made the determination to destroy the drug. The Agency expects that by combining the notice and introduction of testimony on destruction with the notice and introduction of testimony on refusal of admission, any additional storage time at an express courier due to implementation of section 708 of FDASIA will be minimal.

An express courier is not liable for the storage or destruction costs under section 801(c) of the FD&C Act unless that courier is also the owner or consignee of a destroyed drug, which would be unusual. As stated in the proposed rule, if a drug is sent by international mail, FDA generally considers the addressee of the parcel to be the owner or consignee of the drug.

(Comment 5) One commenter requested that FDA clearly define and outline the storage and destruction costs to consumers under section 801(c) of the FD&C Act and that the Agency provide offsets to those costs for consumers unable to pay due to financial stress.

(Response 5) FDA generally does not intend to pursue recovery of storage and destruction costs under section 801(c) of the FD&C Act against individual consumers who seek to import a drug for their own personal use that is then refused and destroyed by the Agency under section 708 of FDASIA.

D. General Comments

The final rule provides the owner or consignee of a drug 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 with: (1) Written notice that FDA intends to destroy the drug and (2) an opportunity to present testimony to the Agency before the drug is destroyed.

(Comment 6) Many comments made general remarks expressing support or opposition to the authority granted to FDA by section 708 of FDASIA to administratively destroy certain refused drugs and did not focus on the rule or a particular section of the rule.

One comment supported the administrative destruction of certain refused drugs while several comments expressed concern about the potential impact of administrative destruction on a consumer's access to foreign drugs. These comments cited a patient's inability to comply with a drug treatment plan as a consequence of that lack of access. One comment requested that FDA change its current Personal Importation Policy to allow importation of any drug from a "safe" foreign pharmacy or for which there is a "valid" prescription. The comment further requested that FDA define the term "safe personal drug import" in the final rule.

(Response 6) As required for implementation of section 708 of FDASIA, the final rule provides appropriate due process to the owner or consignee of a drug that has been refused admission under section 801(a) of the FD&C Act, and that FDA intends to destroy. The new authority granted to FDA by section 708 of FDASIA to administratively destroy a drug applies only after the Agency has made the final decision to refuse admission to the drug. This new authority, therefore, does not affect a consumer's access to a foreign drug because consumers have no access to a refused drug under the FD&C Act. The final rule does not modify FDA's current policy with respect to personal importation of drugs.

(Comment 7) One comment suggested that implementation of section 708 of FDASIA could adversely affect the supply of low-value excipients and other drug components potentially leading to a drug shortage. The commenter suggested that FDA closely coordinate with manufacturers to limit the impact on the drug supply chain when the Agency exercises its authority to destroy low-value excipients or other drug components. The commenter further suggested that FDA's Drug Shortages Task Force monitor and publicly report on the effects of section 708 of FDASIA on the drug supply in the United States.

(Response 7) Excipients and other components of a drug are defined as drugs under section 201(g)(1) of the FD&C Act. An excipient or other drug component is therefore subject to administrative destruction under section 708 of FDASIA if that excipient or drug component offered for import is valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) and is refused admission. FDA does not expect that administrative destruction of refused excipients or other drug components will lead to shortages of medically necessary drugs. The majority of excipients and drug components are imported into the United States as commercial entries. Currently, where excipients or drug components are

refused admission, they are exported or destroyed. Refused excipients or other drug components, therefore, are not currently available for drug manufacturing in the United States. The Agency's exercise of administrative destruction will not affect a manufacturer's access to these refused excipients or other drug components and, therefore, will not contribute to shortages of drugs manufactured in the United States.

(Comment 8) One comment asserted that FDA only quantified the benefits but not the costs of the proposed rule which, according to the comment, should include the societal costs attributable to a patient's lack of access to an imported drug that does not pose a public health risk, and that patient's non-adherence to a medical plan that includes such drug.

(Response 8) In the proposed rule, FDA estimated both the costs and the benefits of the implementation of section 708 of FDASIA and the result was a quantifiable net annual social benefit. The detailed analysis of the estimated economic impact as provided in Ref. 10 in the proposed rule can be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#.

The preliminary Regulatory Impact Analysis did not include any costs attributable to lack of access to an imported drug by a patient as this is not a cost attributable to administrative destruction. Currently, drugs that are refused admission are destroyed or exported by the importer or, in the case of international mail, returned to the USPS for export. Consequently, patients do not have access to those drugs. Only refused drugs are subject to administrative destruction under section 708 of FDASIA and, therefore, implementation of this authority does not result in a quantifiable cost to be included in the regulatory impact analysis of the implementation of section 708.

(Comment 9) A number of comments requested that FDA flag shipments in Customs and Border Protection's Automated Commercial System (ACS) or the Automated Commercial Environment (ACE) system, which is expected to replace ACS by December 2016, when a drug is destroyed. Another comment suggested that FDA establish a public database listing drugs destroyed by FDA under the authority of section 708 of FDASIA.

(Response 9) These comments relate to the Agency's operations implementing the final rule and, as FDA stated in the proposed rule, the Agency plans to specify the operational details of its process for destruction by guidance, operating guidelines, or similar means.

IV. Analysis of Impacts (Summary of the Final Regulatory Impact Analysis)

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 this 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 finalizing "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.

The primary public health benefit from adoption of the 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 final 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 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 U.S. 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.

The estimated primary costs to FDA 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 of the RPM and other internal import operations guidelines, and training for FDA personnel. Our estimates of the primary costs assume that all

refused drugs valued at $2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation) would be destroyed (estimated 15,100 destructions performed each year), that FDA would 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 refusal of drugs. The assumption that FDA 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.

Based on an assumed 15,100 administrative destructions performed each year, the Agency estimates the quantifiable net annual effect of the final rule to be between a cost of $54,325 and a cost savings of $901,950, in addition to one-time costs of $531,670. Annualized over 20 years, the final rule is estimated to produce a net effect 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.

Our estimates do not include net benefits of the final rule because we have not quantified the potential health benefits of reducing the probability that a refused drug will be imported into the United States in the future. 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.

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 with FDA bearing most of the cost as the Agency is responsible under section 708 of FDASIA for implementation of the rule and for the costs of storage and destruction. 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.

The full discussion of economic impacts, which includes a list of changes made in the final regulatory impact analysis, is available in Docket No. FDA-2014-N-0504 and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm# (Ref. 1).

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)). Therefore, clearance by the Office of Management and Budget is not required under the Paperwork Reduction Act of 1995.

VI. Federalism

FDA has 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, the Agency has concluded 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.

VII. Environmental Impact

The Agency has 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.

VIII. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at http://www.regulations.gov. (FDA has verified the Web site address in this Reference section, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, and Final Unfunded Mandates Reform Act Analysis for Administrative Destruction of Certain Drugs Refused Admission to the United States, available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm#.

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, 21 CFR part 1 is amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR 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, 343, 350c, 350d, 352, 355, 360b, 360ccc, 360ccc-1, 360ccc-2, 362, 371, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Revise § 1.94 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 that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director shall give the owner or consignee a written 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.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the district

director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the district director may give the owner or consignee a single written notice that provides the notice on refusal of admission and the notice on destruction of an article described in paragraph (a) of this section. The district 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: September 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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