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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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

Administrative Destruction of Certain Drugs Refused Admission to the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing a regulation to implement 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 (FD&C Act), by providing to the owner or consignee notice and an opportunity to appear and introduce testimony to the Agency prior to the destruction. The proposed regulation is authorized by amendments made to the FD&C Act by the Food and Drug Administration Safety and Innovation Act (FDASIA). Once finalized, this proposed regulation 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: Submit either electronic or written comments on the proposed rule by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2014-N-0504, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2014-N-0504 for this rulemaking. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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 Proposed Rule

The proposed rule would provide 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. 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 these refused drugs 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 (Pub. L. 112-144).) This provision, as well as section 701 of the FD&C Act (21 U.S.C. 371), provide the legal authority for this proposed rule.

Summary of the Major Provisions of the Proposed Regulatory Action

This proposed rule would provide 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) notice and an opportunity to present testimony to the Agency before the drug is destroyed.

FDA proposes to amend part 1 (21 CFR part 1) by expanding the scope of § 1.94 (21 CFR 1.94). Currently this regulation 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 proposed rule would expand the scope of § 1.94 to provide an owner or consignee with notice and opportunity to present testimony to the Agency prior to the destruction of certain refused drugs.

Costs and Benefits

The primary public health benefit from adoption of the proposed 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 that 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 proposed rule, if finalized, include the additional costs to destroy a violative drug. The Agency estimates the quantifiable net annual social benefit of the proposed rule to range between $228,000 and $618,000.

I. Background and Legal Authority

On July 9, 2012, President Obama signed FDASIA into law. 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 in section 708, 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. Section 708 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 pursuant to section 801(c) of the FD&C Act.

FDA is issuing this proposed rule to implement section 708 of FDASIA. That provision directs FDA to issue regulations that provide 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 has been refused admission 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. FDA is also issuing this proposed rule under section 701(b) of the FD&C Act, which authorizes regulations for the efficient enforcement of section 801 of the FD&C Act.

A drug 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 is or appears to be adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act (21 U.S.C. 355). Under current regulation § 1.94, FDA issues a notice of the Agency's intention to refuse a drug to the owner or consignee, as defined in § 1.83, stating the reasons for the intended refusal. If the article is sent by international mail, FDA generally considers the addressee of the parcel to be the owner or consignee. If this notice is to an individual who is importing a drug for personal use, it is issued consistent with the requirements of section 801(g) of the FD&C Act. The owner or consignee is given an opportunity to appear before the Agency and introduce testimony orally or in writing on why the drug should not be refused admission into the United States. The owner or consignee can also submit an application for authorization to recondition the drug to bring it into

compliance with the FD&C Act or to render it other than a food, drug, device, or cosmetic. If, after providing the owner or consignee with notice and opportunity to present testimony, FDA determines that the drug should be refused admission, a notice of such refusal is issued to the owner or consignee.

The majority of refused drug products subject to FDA's new destruction authority come into the United States via an International Mail Facility (IMF) or an express courier hub. Parcels that come into the United States via an IMF are routed by the United States Postal Service (USPS) to Customs and Border Protection (CBP). CBP interdicts certain drug shipments and turns them over to FDA for examination and a determination of admission under the FD&C Act. Some of these parcels may include one or more drugs that are unapproved, adulterated and/or misbranded, including counterfeit drugs and drugs that purport to be dietary supplements. USPS estimated that the average daily number of parcels that came into the United States via international mail from November 1, 2011, to October 31, 2012, was nearly 1.2 million (Ref. 1). 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.

Operation Safeguard is a multiagency initiative to target illicit imports of prescription drugs. In total, from fiscal years 2010 through 2012, FDA examined nearly 45,000 shipments and CBP seized more than 14,000 illicit shipments of prescription drugs during Operation Safeguard, with international mail shipments constituting the majority of the shipments that were seized (Ref. 1). Despite these efforts, the high volume of inbound international mail shipments has strained limited Federal resources at the IMFs making it extremely difficult to interdict all incoming shipments of violative drugs.

Violative drugs pose a serious public health threat to consumers in the United States because they might not contain the active ingredient that patients need for the treatment of their disease; they might have too much or too little of an active ingredient; they might contain the wrong active ingredient; and/or they might contain toxic ingredients. For certain classes of drugs (e.g. antibiotics), these quality problems can also increase the likelihood of drug resistance (Ref. 2). By taking these drugs, consumers may be harmed directly by exposure to unsafe drugs or they may be harmed because they are prevented from getting the appropriate dose or strength of medications they need. Adverse events due to these violative drugs are underreported. Patients taking ineffective drugs may die or suffer the adverse effects of the underlying disease, making it difficult to detect or attribute these consequences to the violative drug (Ref. 3).

FDA has issued several warnings about counterfeit and unapproved drugs, including warnings issued in 2012 and 2013 about counterfeit versions of the cancer medicines AVASTIN and ALTUZAN (bevacizumab) approved for marketing outside of the United States, that were purchased by medical practices in the United States. Certain counterfeit versions of these drugs did not contain the active pharmaceutical ingredient, (bevacizumab), which may have resulted in patients not receiving needed therapy (Ref. 4). In July 2013, a British citizen was sentenced to 18 months in prison for distributing adulterated cancer drugs and selling a counterfeit version of ALTUZAN that was obtained from Turkey to physicians in the United States (Ref. 5). As of December 2013, FDA has issued over 1500 letters to medical practices in the United States to educate them about risky buying practices and to warn them about counterfeit and unapproved drugs in U.S. distribution. FDA publishes warnings about counterfeit medications on its Web site at

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/default.htm.

Many violative drugs are purchased by U.S. consumers over the Internet. 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. These rogue pharmacies may also operate in violation of laws relating to fraud, money laundering and/or intellectual property rights. Rogue Internet pharmacies operate Web sites that may look professional and legitimate, but in reality are often marketplaces for unapproved, adulterated and/or misbranded drugs (Ref. 6). According to the GAO report, LegitScript, an online pharmacy verification service that assesses the legitimacy of Internet pharmacies, determined that there were over 34,000 active rogue Internet pharmacies as of April 2013 (Ref. 7).

FDA has received a number of reports of adverse events resulting from the purchase of violative drugs over the internet. For example, FDA received reports from several consumers who ordered the FDA-approved drugs AMBIEN, XANAX, LEXAPRO, or ATIVAN over the Internet but instead received products containing haloperidol (the active pharmaceutical ingredient in the FDA-approved antipsychotic drug HALDOL). These consumers required emergency medical treatment for symptoms such as difficulty in breathing, muscle spasms, and muscle stiffness--all drug reactions associated with this powerful antipsychotic (Ref. 8). In May 2012, FDA warned consumers about a counterfeit version of ADDERALL (a drug used to treat attention deficit hyperactivity disorders and narcolepsy) containing the wrong active pharmaceutical ingredients, that was being purchased on the Internet (Ref. 9).

Some drugs that are represented and sold as dietary supplements can also present a significant public health risk. For example, some purported dietary supplements actually contain hidden or deceptively labeled active pharmaceutical ingredients, some at levels much higher than those found in drug products that are the subject of approved applications. Such products, especially when taken without physician supervision, can cause harm and have been associated with serious adverse events. Some purported dietary supplements, although they may not contain harmful ingredients, present a significant indirect public health risk because they are promoted to prevent or treat serious diseases but have not been proven safe and effective for that purpose. Instead of seeing a doctor for diagnosis and treatment, naïve consumers may rely on such unproven remedies and may even substitute them for doctor-prescribed medications that have been approved by FDA based on proof of safety and effectiveness.

Approximately 60 percent of the Class I drug recalls for fiscal years 2007 through 2013 involved drugs purported to be dietary supplements. (Class I drug recalls involve public health threats for which there is a reasonable probability that the use of or exposure to a drug will cause serious adverse health consequences or death.) Many of the drugs being unlawfully marketed as dietary supplements are imported into the United States via IMFs and express courier hubs.

Currently, drugs that have been refused admission into the United States under section 801(a) of the FD&C Act are destroyed unless they are exported within 90 days. Certain illegal drugs may also be destroyed if they are seized and condemned under FDA's seizure authority, section 304 of the FD&C Act (21 U.S.C. 334), or if they are seized and forfeited under CBP's seizure and forfeiture authority, such as 19 U.S.C. 1595a(c). Drugs that are imported via an IMF which are refused are sent back to the USPS for export. There is currently little deterrence to prevent sellers from sending violative drugs or resending previously refused drugs into the

United States via the IMFs. Drugs refused admission into the United States might be subsequently offered for re-importation by unscrupulous sellers who choose to circumvent the import regulatory systems. In fact, some of the parcels returned by USPS have been resubmitted for entry into the United States by the sender, with the sticker indicating prior refusal by FDA still attached and visible. Under this proposed rule, FDA will be better able to prevent such re-importation by having an administrative mechanism for destroying 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.

II. Proposed Changes to Current Regulations

A. Proposed Revisions to Part 1

FDA proposes to amend part 1 to create an implementing regulation for the administrative destruction of refused drugs. The proposed amendment to part 1 consists of amendments to § 1.94.

B. Principal Features of the Proposed Rule

Section 708 of FDASIA authorizes the Agency to destroy certain drugs that have already been refused admission under section 801(a) of the FD&C Act after the owner or consignee receives notice and an opportunity to present testimony before the Agency prior to destruction. The proposed rule allows 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. As with refusal of admission, FDA plans to specify operational details of its process for destruction

by guidance, operating guidelines, or similar means. For example, the proposed rule says the notice will specify a time period for introducing testimony regarding destruction, which may be adjusted upon timely request giving reasonable grounds, and FDA could explain the time period it would typically provide. The operational details could also include the format of the notice and which FDA officials are authorized to make the decision as to whether to destroy a particular drug.

As noted, a drug is subject to refusal of admission if, among other reasons, it is or appears to be adulterated, misbranded, or unapproved in violation of section 505 of the FD&C Act. FDA intends to exercise its new authority under section 708 of FDASIA to take the further step of destroying a drug only in situations where, after providing the owner or consignee with the opportunity to introduce testimony, the Agency has made a determination that the drug is adulterated, misbranded, or unapproved in violation of section 505.

III. Effective Date

FDA intends that the effective date of the new requirements will be 30 days after publication of a final rule in the Federal Register. Section 708 of FDASIA states that FDA's new authority under section 801(a) of the FD&C Act shall not take effect until FDA issues a final regulation, and section 708 of FDASIA requires FDA to "publish the final regulation not less than 30 days before the regulation's effective date."

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

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612) and the Unfunded Mandates Reform Act of 1995 (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 proposed rule, if finalized, would not be an economically significant regulatory action as defined by Executive Order 12866.

If a rule has a significant economic impact on a substantial number of small businesses, the Regulatory Flexibility Act requires Agencies to analyze regulatory alternatives that would minimize any significant impact of a rule on small entities. As further explained in this section, FDA has determined that this proposed rule, if finalized, would 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 (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule, if finalized, to result in any 1-year expenditure that would meet or exceed this amount.

The primary public health benefit from adoption of the proposed rule would 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 proposed 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.

The estimated primary costs to FDA include the additional costs associated with destroying a refused drug. 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 12,100 destructions performed each year), that FDA would contract with another Government agency or private firm to destroy the drug, and the notice and hearing process for destruction would likely be combined with the notice and hearing process for refusals. Based on an assumed 12,100 administrative destructions performed each year, the Agency estimates the quantifiable net annual social benefit of the proposed rule, if finalized, to be between $228,000 and $618,000. The present discounted value of the quantifiable net social benefit over 20 years would be in the range of $3,386,000 to $9,169,000 at a 3 percent discount rate and in the range of $2,411,000 to $6,529,000 at a 7 percent discount rate.

FDA has examined the economic implications of the proposed 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. In the proposed rule, small entities will bear costs to the extent that they are responsible for the violative product. The number of expected destructions per year along with the very small value per event implies that

this burden would not be significant, so we find that this proposed rule, if finalized, would 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 Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

The full discussion of economic impacts is available in docket FDA-2014-N-0504 and at http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm# (Ref. 10).

V. Paperwork Reduction Act of 1995

FDA concludes that the requirements contained in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3518(c)(1)(B)(ii)).

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed 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. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Government Accountability Office. "Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad," (GAO-13-560), p. 29 , 2013. http://www.gao.gov/products/GAO-13-560.

2. U.S. Food and Drug Administration. "Remarks as Delivered of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Partnership for Safe Medicines Interchange," 2010.

http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf.

3. Institute of Medicine. "Countering the Problem of Falsified and Substandard Drugs." Washington, D.C.: The National Academies Press, p. 57, 2013. http://books.nap.edu/openbook.php?record_id=18272.

4. U.S. Food and Drug Administration. "Health Care Provider Alert: Another Counterfeit Cancer Medicine Found in the United States," 2013. http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/ucm338283.htm.

5. Department of Justice, United States Attorney's Office for the Eastern District of Missouri. "English Citizen Sentenced for Distributing Adulterated and Counterfeit Cancer Drugs," 2013. http://www.justice.gov/usao/moe/news/2013/july/taylor_richard.html.

6. Government Accountability Office. "Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rogue Sites, Particularly Those Abroad," (GAO-13-560), What GAO Found, 2013. http://www.gao.gov/products/GAO-13-560.

7. Id., p. 14.

8. U.S. Food and Drug Administration. "The Possible Dangers of Buying Drugs Over the Internet," 2011. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm.

9. U.S. Food and Drug Administration. "FDA Warns Consumers about Counterfeit Version of Teva's Adderall," 2011. http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm305932.htm.

10. U.S. Food and Drug Administration. "Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Administrative Destruction of Certain Drugs Refused Admission to the United States," 2014. 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, it is proposed that 21 CFR part 1 be amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 is revised 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: April 30, 2014.

Leslie Kux,
Assistant Commissioner for Policy.

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