Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 12, 113, 151, and 162

RIN 1515-AC87

Dog and Cat Protection Act

AGENCY: Customs Service, Treasury. **ACTION:** Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations to implement certain provisions of the Dog and Cat Protection Act of 2000. The Dog and Cat Protection Act of 2000 prohibits the importation of any products containing dog or cat fur, and provides for civil and criminal penalties for violations of the Act. This document proposes to set forth in the regulations the prohibitions on dog and cat fur importations and the penalties for violations. The document also proposes to implement the provision of the Act pertaining to Customs certification of domestic and foreign commercial laboratories to test products to determine if the products intended to be imported into the United States contain dog or cat fur. The proposed regulations implement Federal law prohibiting these imports in order to discourage inhumane practices abroad concerning the treatment of dogs and cats.

DATES: Comments must be received on or before October 9, 2001.

ADDRESSES: Written comments may be addressed to, and inspected at, U.S. Customs Service, Office of Regulations and Rulings—Regulations Branch, 1300 Pennsylvania Avenue—3rd Floor, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: On laboratory procedures—Renee Stevens, Laboratories & Scientific Services, Office of Information and Technology, (202) 927–0941;

On trade enforcement matters—Luan T. Cotter, Trade Programs—Commercial Enforcement, Office of Field Operations, (202) 927–1249; and On penalty and forfeiture policy and procedural matters—Jeremy Baskin, Penalties Branch, Office of Regulations and Rulings, (202) 927–2344.

SUPPLEMENTARY INFORMATION:

Background

I. The Dog and Cat Protection Act of 2000, in General

Congress found that products made with dog and cat fur are being imported into and sold in the United States and that these products are often deceptively labeled to prevent consumers, as well as retailers and importers, from ascertaining the true content of the fur contained in the products they purchase in the U.S. Congress also found that available evidence suggests that producers of dog and cat fur products house, transport, and slaughter these dogs and cats for their fur in inhumane ways. Based on these findings, Congress promulgated the Dog and Cat Protection Act of 2000 (the "Act"), as chapter 3 of Subtitle B of Title I of the Tariff Suspension and Trade Act of 2000. This Act was signed into law on November 9, 2000 (Pub. L. 106-476, 114 Stat. 2101, codified at 19 U.S.C. 1308).

The provisions of the Act amend Title III of the Tariff Act of 1930 by adding a new section 308, entitled "Prohibition on importation of dog and cat fur products." In general, the provisions of the new section 308 prohibit the importation, exportation, introduction into interstate commerce, manufacture for introduction into interstate commerce, offer for sale, sale, transportation, or distribution in the U.S. of any products made with dog or cat fur. This section also provides for civil and criminal penalties for violations of the Act, including the forfeiture of prohibited products and the potential debarment of individuals from engaging in commerce involving fur products. Further, section 308 also authorizes the Secretary of the Treasury to offer rewards for information concerning violations, and provides any persons accused of certain violations with an affirmative defense if they can demonstrate that they exercised reasonable care in determining the nature of the products alleged to have been imported or exported in violation of the Act. Lastly, this section directs Customs to develop a program of certifying U.S. and foreign laboratories for making reliable assessments of

whether products are made with dog or cat fur.

This document proposes to amend the Customs Regulations (19 CFR chapter I) to set forth the prohibited conduct defined in the Act. The document also proposes to set forth the penalty, forfeiture, and reward provisions, and the provision regarding the affirmative defense of reasonable care for persons accused of violating provisions of the Act. In addition the document proposes to implement the provision regarding the accreditation of domestic and foreign laboratories for testing products to determine if the products contain dog or cat fur.

II. Specific Provisions of the Dog and Cat Protection Act of 2000

A. Prohibited Conduct

For Customs purposes, the Act prohibits any person from importing into, or exporting from, the U.S. any dog or cat fur product. The Act provides an exception for the importation, exportation, or transportation, for noncommercial purposes, of deceased personal pets, that includes such pets preserved through taxidermy. The terms "cat fur," "dog fur," "dog or cat fur product," and "person" are specifically defined in the Act.

Prohibited and restricted merchandise are generally provided for in part 12 of the Customs Regulations. It is proposed to add a new subheading for dog and cat fur and to add a new § 12.64 to provide for the Act's provisions pertaining to the prohibited conduct. The definitions for the terms "cat fur," "dog fur," "dog or cat fur product," and "person" will be provided for at paragraph (a) of the new § 12.64. The nature of the prohibited conduct will be provided for at paragraph (b) of the new § 12.64. Paragraph (c) will provide that any products containing dog or cat fur imported or exported contrary to the provisions of § 12.64 are subject to seizure and forfeiture.

B. Penalty and Reward Provisions

The Act provides that any person who violates any provision of new section 308, in addition to any other civil or criminal penalty that may be imposed under title 18 of the United States Code or any other provision of law, may be assessed a civil penalty of not more than \$10,000 for each separate knowing and intentional violation, \$5,000 for each

separate grossly negligent violation, or \$3,000 for each separate negligent violation. Further, the violator may be prohibited from importing, exporting, or selling any fur product in the United States if it is found that the person engaged in a pattern or practice of actions that has resulted in a final administrative determination with respect to the assessment of civil penalties for knowing and intentional or grossly negligent violations of section 308. In determining the amount of civil penalties assessed for violation of section 308, the degree of culpability, any history of prior violations, ability to pay, the seriousness of the violation, and any other matters as fairness may require will be taken into account. No penalty will be assessed under the Act against a person unless the person is given written notice and an opportunity for a hearing. Lastly, a reward of not less than \$500 will be paid to any person who furnishes information that establishes or leads to a civil penalty assessment, debarment, or forfeiture of property for any violation of the Act.

These penalty and reward provisions are proposed to be provided for at paragraphs (b)-(d) of new § 162.81. Paragraph (a) of new § 162.81 will reference the prohibited conduct provided for at new § 12.64.

C. The Affirmative Defense of Reasonable Care

Any person charged with a penalty under the provisions of the Act has a defense to that proceeding if he establishes that he exercised reasonable care in determining the nature of the products alleged to have resulted in such violation, and in ensuring that the products were accompanied by documentation, packaging, and labeling that were accurate as to the nature of the products. One of the procedures prescribed by the Act as an indicia of reasonable care is use of a Customsaccredited laboratory's determination that dog or cat fur is not contained in an item. While the use of a Customsaccredited laboratory is not required to avoid liability, it may prove dispositive in determining whether the person exercised reasonable care.

This affirmative defense provision is proposed to be provided for in paragraph (e) of new § 162.81.

D. Customs Accreditation of Fur Testing Laboratories

Section 151.12 of the Customs Regulations (19 CFR 151.12) concerns the accreditation of commercial laboratories. Paragraph (b) of § 151.12 explains, in general, what a Customsaccredited laboratory is and provides

that accreditation is restricted to facilities within the United States that analyze certain commodities to determine elements relating to the admissibility, quantity, composition, or characteristics of imported merchandise. Because the Act requires Customs to provide for a process by which accreditation will be extended to foreign testing laboratories that can demonstrate to Customs reliable assessments of whether products intended for sale or consumption in the United States are made with dog or cat fur, it is proposed to amend this paragraph by adding another sentence to explain Customs limited accreditation of foreign laboratories to analyze products to determine if they contain dog or cat fur.

Regarding the process by which testing laboratories, whether domestic or foreign, can qualify for certification by Customs, the application and accreditation procedures currently provided for at § 151.12 and the fee schedule explained in T.D. 99-67 will apply. Paragraph (d) of § 151.12 currently provides that accreditation may be sought by a commercial laboratory in any commodity group listed in paragraph (d)(2) of the section, and explains that applicable test procedures are listed in Commodity Group Brochures. To provide for Customs accreditation of commercial laboratories for purposes of the Act, Customs proposes to amend paragraph (d)(2) to add a new subparagraph (xvi) that will provide for the accreditation of laboratories in the testing of products containing fur, regardless of the classification of the products under the tariff schedule (HTSUS), to determine if the products contain any dog or cat fur. Customs will provide for the dog and cat fur testing procedures in a new Commodity Group Brochure. This proposed amendment will also reference the provisions of proposed §§ 12.64 and 151.12(b) discussed above.

With the accreditation of foreign laboratory facilities by Customs, further amendments are required regarding bonding, the payment of accreditation/ reaccreditation fees, and laboratory operations because the present regulatory scheme only concerns laboratory facilities located and operations occurring in the United

Regarding bonding, paragraph (f)(1)(vii) of § 151.12 concerns the agreement of laboratories to execute a bond when notified of pending accreditation and references the provisions of part 113 of the Customs Regulations. The bond conditions for commercial laboratories are at

§ 113.67(b), which provides, in part, that if the principal defaults, the obligors must pay liquidated damages and that if the merchandise is restricted merchandise the liquidated damages are equal to three times the value of the merchandise.

Because the risk of malfeasance or nonperformance presented by foreign laboratories accredited by Customs is great, given the distance and lack of enforcement opportunities, and because prohibited, not merely restricted, merchandise is at issue, the following amendments are proposed. First, it is proposed to amend § 151.12(f)(1)(vii) to provide that when laboratories located outside of the United States are notified of pending accreditation/ reaccreditation, a bond in the amount of a minimum of \$ 1 million will be required to be executed in accordance with the provisions of part 113 of the Customs Regulations. Also, to secure the payment of any liquidated damages which may be assessed against the laboratory, it is proposed to further amend § 151.12(f)(1)(vii) to provide that the foreign laboratory have a designated resident corporate surety in the United States. It is also proposed to amend the provisions of § 113.67(b)(2)(i) to provide that if the principal defaults in the case of a bond taken by a foreign laboratory accredited to test products to determine if the products contain dog or cat fur, the obligors agree to pay liquidated damages equal to nine times the value of the merchandise.

Paragraphs (f)(1)(xi) and (h)(1)(i) of § 151.12 concern the fee requirements for accreditation/reaccreditation of commercial laboratories. With the accreditation of foreign laboratories, foreign exchange rate fluctuationsrespecting assessed costs—and the payment of variable fee assessments for international travel, per diem and background expenses prior to Customs review of an application for accreditation become issues. Accordingly, it is proposed to amend the second sentences of these provisions to limit their scope to domestic laboratories and to add new third sentences to provide that foreign laboratories applying for accreditation/ reaccreditation must submit the whole of variable charges assessed for international travel, per diem and background expenses in U.S. currency before Customs will undertake to review their application for accreditation.

A change is also needed to paragraph (j) of § 151.12, which concerns how Customs-accredited laboratories should operate. Paragraph (j)(1) explains the procedure to be followed regarding the testing of sample merchandise. The

paragraph requires Customs supervision when merchandise samples are split for testing by accredited laboratories. Since the dog and cat fur-testing operations of foreign laboratories will be outside of the United States, Customs cannot supervise the procedure regarding the splitting of samples. Accordingly, this regulatory provision must be amended. It is proposed to amend paragraph (j) by adding a sentence that provides that the requirements regarding samples only apply to domestic laboratory operations and not to foreign laboratory operations accredited for purposes of the Dog and Cat Protection Act of 2000. Another sentence will be added to require that if a foreign laboratory accredited by Customs to test for dog and cat fur certifies that the product does not contain dog or cat fur, the certification submitted by an importer must be accompanied by the reports of the laboratory's testing result.

III. Miscellaneous and Organizational Change

On September 21, 2000, the Commissioner of Customs announced certain organizational changes at Customs. One of these changes involved reassigning oversight of the Laboratories & Scientific Services from the Assistant Commissioner, Office of Field Operations, to the Assistant Commissioner, Office of Information and Technology (OIT). This action was taken so that Laboratories & Scientific Services could take better advantage of the technical expertise and services offered by OIT. Because the regulations providing for commercial laboratories expressly reference the Office of Field Operations at § 151.12(a), it is proposed to amend this provision to reference the Office of Information and Technology.

Comments

Before adopting these proposed regulations as a final rule, consideration will be given to any written comments timely submitted to Customs, including comments on the clarity of this proposed rule and how it may be made easier to understand. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4 of the Treasury Department Regulations (31 CFR 1.4), and § 103.11(b) of the Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1300 Pennsylvania Avenue—3rd Floor, NW, Washington, D.C.

The Regulatory Flexibility Act And Executive Order 12866

Pursuant to provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), it is certified that, if adopted, the proposed amendments will not have a significant economic impact on a substantial number of small entities. The proposed amendments merely set forth statutory prohibitions on the importation of products containing dog and cat fur and provide for a laboratory certification process that Customs has been directed to implement. Accordingly, the proposed amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604. This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Paperwork Reduction Act

The collection of information in the current regulations has already been approved by the Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) and assigned OMB control number 1515–0155 (Application and other documents pertaining to accreditation of commercial laboratories). This notice of proposed rulemaking does not involve any material change to the existing approved information collection.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB.

Part 178 of the Customs Regulations (19 CFR part 178), which lists the information collections contained in the regulations and control numbers assigned by OMB, would be amended accordingly if this proposal is adopted.

List of Subjects

19 CFR Part 12

Animals, Customs duties and inspection, Entry of merchandise, Exports, Furs, Imports, Labeling, Marking, Prohibited merchandise, Reporting and recordkeeping requirements, Restricted merchandise, Seizure and forfeiture.

19 CFR Part 113

Bonds, Customs duties and inspection, Exports, Foreign commerce and trade statistics, Imports, Laboratories, Reporting and recordkeeping requirements, Surety bonds.

19 CFR Part 151

Customs duties and inspection, Examination, Exports, Imports, Laboratories, Licensing, Penalties, Reporting and recordkeeping requirements, Sampling and testing.

19 CFR Part 162

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Inspection, Law enforcement, Penalties, Prohibited merchandise, Restricted merchandise, Reporting and recordkeeping requirements, Seizures and forfeitures.

Proposed Amendments to the Regulations

For the reasons stated above, it is proposed to amend parts 12, 113, 151, and 162 of the Customs Regulations (19 CFR parts 12, 113, 151, and 162) as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general authority citation for part 12 continues, and a new specific authority for new § 12.64 is added, to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 22, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

Section 12.64 also issued under 19 U.S.C. 1308;

2. A new center heading consisting of § 12.64 is added after § 12.63 to read as follows:

Dog and Cat Fur

§12.64 Products containing dog and cat fur prohibited.

(a) *Definitions*. For purposes of this section, the following terms have the meanings indicated:

Cat fur. "Cat fur" means the pelt or skin of any animal of the species Felis catus.

Dog fur. "Dog fur" means the pelt or skin of any animal of the species Canis familiaris.

Dog or cat fur product. "Dog or cat fur product" means any item of merchandise which consists, or is composed in whole or in part, of any dog fur, cat fur, or both.

Person. "Person" means any individual, partnership, corporation, association, organization, business trust, government entity, or other entity subject to the jurisdiction of the U.S.

(b) Prohibited merchandise.—(1) Imported or exported. It is unlawful for any person to import into, or export from, the U.S. any dog or cat fur product.

(2) Exception. The provisions of paragraph (b)(1) of this section do not apply to the importation or exportation for noncommercial purposes, of deceased personal pets, including such pets preserved through taxidermy.

(c) Forfeiture. Any dog or cat fur product imported or exported contrary to the provisions of this section is subject to seizure and forfeiture.

PART 113—CUSTOMS BONDS

1. The general authority citation for part 113 continues to read as follows:

Authority: 19 U.S.C. 66, 1623, 1624. * * * *

2. In § 113.67(b)(2)(i), a new sentence is added to the end to read as follows:

§113.67 Commercial gauger and commercial laboratory bond conditions.

* * * (b) * * *

(2) * * *

(i) * * *. If the principal defaults in the case of a bond taken by a foreign laboratory accredited to test products to determine if the products contain dog or cat fur, the obligors agree to pay liquidated damages equal to nine times the value of the merchandise. (See, § 151.12(f)(1)(vii) of this chapter.)

PART 151—EXAMINATION, SAMPLING, AND TESTING OF **MERCHANDISE**

1. The general authority citation for part 151 continues, and a new specific authority citation for § 151.12 is added, to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Notes 22 and 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1624.

Subpart A also issued under 19 U.S.C.

Section 151.12 also issued under 19 U.S.C. 1308;

* *

2. In § 151.12:

- a. Paragraph (a) is amended at the definition for "Assistant Commissioner" by removing the words "Office of Field Operations" and adding, in their place, the words "Office of Information and Technology";
- b. paragraph (b) is amended by revising the second sentence and by adding a new third and fourth sentence;
- c. paragraph (d)(2) is amended by adding a new paragraph (d)(2)(xvi);
- d. paragraph (f) is amended:
- (i) at paragraph (f)(1)(vii) by adding a new sentence at the end of the paragraph;

- (ii) at paragraph (f)(1)(xi) at the second sentence by removing the words "the applicant agrees" and adding, in their place, the words "domestic applicants agree"; and, by adding a new third sentence; and
- (iii) by adding a new paragraph (f)(1)(xii); and
- e. paragraph (h)(1)(i) is amended at the second sentence by removing the words "Before a laboratory" and adding, in their place, the words "Before a domestic laboratory"; and by adding a new third sentence;
- f. paragraph (j)(1) is amended by revising the first sentence and adding a new sentence at the end of the paragraph.

The additions and revisions to read as follows:

151.12 Accreditation of commercial laboratories.

(b) * * *. A "Customs-accredited laboratory" is a commercial laboratory that has demonstrated, to the satisfaction of the Executive Director, pursuant to this section, the capability to perform analysis of certain commodities to determine elements relating to the admissibility, quantity, composition, or characteristics of imported merchandise. For accreditations other than accreditation to determine whether dog or cat fur is contained in articles, a commercial laboratory must be located in the United States. For accreditation to determine whether dog or cat fur is contained in any articles intended for sale or consumption in the United States, a commercial laboratory may be located

(d) * * * (2) * * *

(xvi) Products, regardless of the chapter of the tariff schedule (HTSUS) under which they are classified when entered, to determine if they contain any dog or cat fur (see §§ 12.64, 151.12(b), and 162.81 of this chapter).

in a foreign country or the United

* * (f) * * * (1) *

(1) * * *

States. * * *

(vii) * * *. If the commercial laboratory is seeking accreditation for determination of whether a product contains dog or cat fur and is located outside of the United States, the express agreement must provide that the foreign laboratory will execute a bond in accordance with part 113, Customs Regulations, in an amount of a minimum of \$1 million, will submit the bond to Headquarters, and that the laboratory will have a resident corporate

surety in the United States to secure the payment of any liquidated damages that may be assessed against the laboratory; the application in this instance must identify the name and address of the resident corporate surety.

* * * (xi) * * *. Foreign applicants applying for accreditation/ reaccreditation regarding the testing of products for dog and cat fur (see §§ 12.64, 151.12(b), and 162.81 of this chapter) must submit all variable charges assessed for international travel, per diem and background expenses in U.S. currency before Customs will undertake to review their application for accreditation.

(xii) If a commercial laboratory is seeking accreditation for determination of whether a product contains dog or cat fur and is located outside of the United States, the name and address of a resident agent in the United States who is authorized to accept service of process against the foreign laboratory.

* *

(h) * * *

(1) * * *

(i) * * *. Foreign laboratories applying for accreditation/ reaccreditation regarding the testing of products for dog and cat fur (see §§ 12.64, 151.12(b), and 162.81 of this chapter) must submit all variable charges assessed for international travel, per diem and background expenses in U.S. currency before Customs will undertake to review their application for accreditation. * *

(j) How will Customs-accredited laboratories operate.—(1) Samples for testing. For laboratories other than those foreign laboratories accredited to determine whether a product contains dog or cat fur, upon request by the importer of record of merchandise, the port director will release a representative sample of the merchandise for testing by a Customsaccredited laboratory at the expense of the importer. * * *. If a foreign laboratory accredited by Customs to test for dog and cat fur certifies that the product does not contain dog or cat fur, the certification submitted by an importer must be accompanied by the reports of the laboratory's testing result as set forth in paragraph (j)(2) of this section.

PART 162—INSPECTION, SEARCH, AND SEIZURE

1. The general authority citation for part 162 continues, and a new specific authority for § 162.81 is added, to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1592, 1593a, 1624.

Section 162.81 also issued under 19 U.S.C. 1308;

2. In § 162.70:

a. paragraph (a)(1) is amended by removing the word "and" at the end of the paragraph and adding a semicolon;

b. paragraph (a)(2) is amended by removing the period at the end and adding, in its place, a semicolon and the word "and"; and

c. a new paragraph (a)(3) is added, to read as follows:

§162.70 Applicability.

(a) * * *

(3) Violations of section 308, Tariff Act of 1930, as amended (19 U.S.C. 1308), that occur after November 9, 2000.

3. A new § 162.81 is added, to read as follows:

§162.81 Penalties for importation or exportation of products containing dog or cat fur

(a) Products containing dog or cat fur. Any person importing into, or exporting from, the U.S. any dog or cat fur product in contravention of the provisions of § 12.64 of this chapter is subject to civil penalties and the merchandise is subject to seizure and forfeiture.

(b) Civil monetary penalties.—(1) Assessment under 19 U.S.C. 1308. Any person who imports or exports from the U.S. any dog or cat fur product in contravention of the provisions of § 12.64 of this chapter may, in addition to any other civil or criminal penalty that may be imposed under title 18, United States Code, or any other provision of law, be subject to civil monetary penalties for violation of 19 U.S.C. 1308 of not more than \$10,000 for each separate knowing and intentional violation of this section, or not more than \$5,000 for each separate grossly negligent violation of this section, or not more than \$3,000 for each separate negligent violation.

(2) Assessment under 19 U.S.C. 1592 or 19 U.S.C. 1595a(b). Any person who imports into the U.S. any dog or cat fur product in contravention of the provisions of § 12.64 of this chapter may be assessed, in addition to or in lieu of any other civil monetary penalty or penalties, civil monetary penalties under 19 U.S.C. 1592 or 19 U.S.C. 1595a(b). These penalties will be administered under Part V, Tariff Act of 1930, as amended.

- (3) Notice. In accordance with 19 U.S.C. 1308(c)(1)(D), no penalty may be assessed or imposed under the provisions of paragraphs (b)(1) or (c) of this section against a person unless the person is given notice and opportunity for a hearing with respect to such violation, in accordance with section 554 of title 5, United States Code.
- (4) Factors in assessing penalties. In determining the amount of civil penalties assessed under paragraphs (b)(1) or (c) of this section, the Secretary of the Treasury will take into account the degree of culpability, any history of prior violations under this statute and regulations, ability to pay, the seriousness of the violation, and such other matters as fairness may require.
- (c) Debarment. In accordance with 19 U.S.C. 1308(c)(1)(B), the Secretary of the Treasury may prohibit a person from importing or exporting any fur product into or out of the United States if the Secretary finds that the person has engaged in a pattern or practice of actions that has resulted in a final administrative determination with respect to the assessment of civil monetary penalties for knowing and intentional or grossly negligent violations of § 12.64 of this chapter.
- (d) Reward. The Secretary of the Treasury will pay a reward of not less than \$500 to any person who furnishes information that establishes or leads to a civil penalty assessment, debarment, or forfeiture of property for any violation of 19 U.S.C. 1308 or any regulation issued thereunder.
- (e) Affirmative defense. Any person accused of a violation under 19 U.S.C. 1308 has a defense in any proceeding brought under paragraphs (b)(1) or (c) of this section or 19 U.S.C. 1308 if that person establishes by a preponderance of the evidence that he exercised reasonable care in determining the nature of the products alleged to have resulted in the violation and in ensuring that the products were accompanied by documentation, packaging, and labeling that were accurate as to the nature of the products. If the person can show that the products imported were tested by a Customs-accredited laboratory (see, § 151.12) to attempt to determine the nature of fur contained in an article, the use of a Customs-accredited laboratory may prove dispositive in determining whether that person exercised reasonable care for purposes of applying applicable penalty provisions.

Approved: July 18, 2001.

Charles W. Winwood,

Acting Commissioner of Customs.

Timothy E. Skud,

 $\label{lem:acting Deputy Assistant Secretary of the Treasury.} Acting Deputy Assistant Secretary of the Treasury.$

[FR Doc. 01–20081 Filed 8–9–01; 8:45 am] BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 500

[Docket No. 01N-0284]

RIN 0910-AB71

Import Tolerances

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) (we, the agency) is soliciting comment on issues related to the implementation of the import tolerances provision in section 4 of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish drug residue tolerances (import tolerances) for imported food products of animal origin for drugs that are used in other countries, but that are unapproved new animal drugs in the United States. Food products of animal origin that are in compliance with the import tolerance will not be considered adulterated under the Federal Food, Drug, and Cosmetic Act (the act) and may be imported into the United States. We plan to propose a regulation for establishing import tolerances. We plan to hold a public meeting on import tolerances during the comment period for this advance notice of proposed rulemaking (ANPRM) and intend to consider the comments made at the meeting and in response to this ANPRM in writing the proposed regulation. We also will work with the Food Safety Inspection Service of the United States Department of Agriculture and other Federal agencies in the development of the proposed regulation.

DATES: Submit written or electronic comments by December 10, 2001.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.