

rule that amended 7 CFR 301 and that was published at 60 FR 39835-39837 on August 4, 1995.

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164-167; 7 CFR 2.17, 2.51, and 371.2(c).

Done in Washington, DC, this 23rd day of October 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-26728 Filed 10-26-95; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

[T.D. 95-88]

Addition of Belize to the List of Nations Entitled to Special Tonnage Tax Exemption

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: Pursuant to information provided by the Department of State, the United States Customs Service has found that no discriminating duties of tonnage or imposts are imposed or levied in the ports of Belize upon vessels wholly belonging to citizens of the United States, or upon the produce, manufactures, or merchandise imported in the same from the United States or from any foreign country. Accordingly, vessels of Belize are exempt from special tonnage taxes and light money in ports of the United States. This document amends the Customs Regulations by adding Belize to the list of nations whose vessels are exempt from payment of any higher tonnage duties than are applicable to vessels of the United States and from the payment of light money.

EFFECTIVE DATE: The exemption from special tonnage taxes and light money for vessels registered in Belize became effective on March 7, 1995. This amendment is effective October 27, 1995.

FOR FURTHER INFORMATION CONTACT: Barbara E. Whiting, Entry and Carrier Rulings Branch, (202) 482-7040.

SUPPLEMENTARY INFORMATION:

Background

Generally, the United States imposes regular and special tonnage taxes, and a duty of a specified amount per ton called "light money" on all foreign vessels which enter United States ports

(46 U.S.C. App. 121, 128). However, vessels of a foreign nation may be exempted from the payment of special tonnage taxes and light money upon presentation of satisfactory proof that no discriminatory duties of tonnage or impost are imposed by that foreign nation on U. S. vessels or their cargoes (46 U.S.C. App. 141).

Section 4.22, Customs Regulations (19 CFR 4.22), lists those nations whose vessels have been found to be exempt from the payment of any higher tonnage duties than are applicable to vessels of the United States and from the payment of light money. The authority to amend this section of the Customs Regulations has been delegated to the Chief, Regulations Branch.

Finding

On the basis of information received from the Department of State regarding the absence of discriminating duties of tonnage or impost imposed on U.S. vessels in the ports of Belize, the Customs Service has determined that vessels of Belize are exempt from the payment of the special tonnage tax and light money, effective March 7, 1995. The Customs Regulations are amended accordingly.

Inapplicability of Public Notice and Delayed Effective Date Requirements, the Regulatory Flexibility Act and Executive Order 12866

Because this amendment merely implements a statutory requirement and confers a benefit upon the public, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary; further, for the same reasons, good cause exists for dispensing with a delayed effective date under 5 U.S.C. 553(d)(1) and (3). Since this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch, U. S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 4

Cargo vessels, Customs duties and inspection, Maritime carriers, Vessels.

Amendment to the Regulations

Part 4, Customs Regulations (19 CFR part 4), is amended as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

1. The general authority for Part 4 and relevant specific authority continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1431, 1433, 1434, 1624; 46 U.S.C. App. 3, 91.

* * * * *

Section 4.22 also issued under 46 U.S.C. App. 121, 128, 141;

* * * * *

§ 4.22 [Amended]

2. Section 4.22 is amended by adding "Belize" in appropriate alphabetical order.

Dated: October 23, 1995.

Harold M. Singer,

Chief, Regulations Branch.

[FR Doc. 95-26717 Filed 10-26-95; 8:45 am]

BILLING CODE 4820-02-P

19 CFR Part 12

[T.D. 95-87]

RIN 1515-AB44

Enforcement of ITC Exclusion Orders

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations regarding unfair competition to reflect Customs authority to enforce seizure and forfeiture orders issued by the United States International Trade Commission (ITC). These orders would be issued for articles which had previously been denied entry pursuant to an ITC exclusion order. Such seizure and forfeiture orders may be issued only when the owner, importer or consignee of such articles has previously attempted to import articles subject to an exclusion order into the U.S.; the articles have previously been denied entry; and the owner, importer or consignee has been notified in writing of the previous denial of entry. The amendment sets forth the procedures Customs will follow when seizures are made for violations of the ITC exclusion orders. It also describes the appeal rights and procedures available to parties who have an interest in the seized property.

EFFECTIVE DATE: November 27, 1995.

FOR FURTHER INFORMATION CONTACT: Vicki Allums, Intellectual Property Rights Branch, U.S. Customs Service, (202) 482-6960.

SUPPLEMENTARY INFORMATION:**Background**

Under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337), the International Trade Commission applies U.S. statutory law and the common law of unfair competition to the importation of products into the United States and their subsequent sale in the United States. Section 337 declares unlawful unfair methods of competition and unfair acts in the importation and sale of products in the United States, the threat or effect of which is to destroy or substantially injure a domestic industry, prevent establishment of such an industry, or restrain or monopolize trade and commerce in the United States. Section 337 also declares as unlawful per se infringement of a valid and enforceable U.S. patent, copyright, registered trademark, or mask work; no resulting injury need be found. To obtain relief under section 337, the affected U.S. industry must file a complaint with the United States International Trade Commission (ITC). A formal hearing before an administrative law judge will then be conducted in order to determine whether a violation under section 337 exists. The administrative law judge then issues an initial determination. The initial determination is subject to discretionary review by the ITC, which may affirm, reverse, modify, set aside, or remand the initial determination to the administrative law judge for further proceedings. If it is determined that a violation exists, the ITC may order that any articles found to be in violation of the Act be excluded from entry into the U.S.

Section 1342(a)(5)(B) of the Omnibus Trade and Competitiveness Act of 1988 amended section 337 of the Tariff Act by inserting a new subsection (I). That subsection authorizes the ITC to issue an order providing that any article determined to be imported in violation of the provisions of the law relating to unfair methods of competition and unfair acts in the importation of articles into the United States should be seized and forfeited when certain conditions stated in the law have been met. Any such order issued is to be enforced by the Secretary of the Treasury.

For such an order to be valid, the law provides that the following conditions must be met:

(a) The owner, importer, or consignee of the article must have previously attempted to import the article into the United States;

(b) The article must have been denied entry into the United States by reason of

an order issued under 19 U.S.C. 1337(d); and

(c) Upon such previous denial of entry, the Secretary of the Treasury must have provided the owner, importer, or consignee of the article with written notice of—

(i) Such order, and

(ii) That seizure and forfeiture would result from any further attempt to import the article into the United States.

Section 12.39, Customs Regulations (19 CFR 12.39) currently describes the role of the ITC in determining whether an importer has engaged in unfair methods of competition or practices, and the actions the ITC can order in response to the finding of such practices. Among those actions are exclusion from entry and entry under bond of articles imported in violation of fair trade provisions, both of which are cited in § 12.39(b). The authority of the ITC to exclude articles from entry into the United States under section 337 is described in § 12.39(b)(1). Section 12.39(b)(2) permits excluded articles to be entered under a single entry bond pending the finalization of the ITC determination. Finally, § 12.39(b)(3) requires, among other things, that district directors notify each importer or consignee of articles entered under bond pursuant to § 12.39(b)(2) when the determination becomes final, and indicate that the entry of articles is refused.

Customs Notice of Proposed Rulemaking

On May 19, 1994, Customs published a Notice of Proposed Rulemaking in the Federal Register (59 FR 26151), which solicited comments on a proposal to amend the Customs Regulations so that they would reflect Customs authority to enforce seizure and forfeiture orders issued by the International Trade Commission. No comments were received in response to the NPRM.

However, in its internal review of the proposed rule, Customs identified an inconsistency between the proposal and the statute's legislative history. The legislative history indicates that Congress intended to include "like goods" within the scope of section 337 seizure orders. The addition of this phrase to the final regulation does not expand the final rule because Customs seizure and forfeiture authority only extends to articles and like articles which fall within the scope of the ITC order. The phrase merely serves to clarify the extent of that authority.

Summary of Amendment

This document amends § 12.39(b), Customs Regulations (19 CFR 12.39(b))

to reflect both the authority of the ITC to issue seizure and forfeiture orders against articles and like articles for which exclusion orders have been issued under certain conditions and the authority of the Secretary of the Treasury to enforce those orders.

The amendment also sets forth the procedures that Customs, on behalf of the Secretary of the Treasury, will follow when enforcing the order. The procedures provide that when the three statutory conditions are met that allow the ITC to issue a seizure and forfeiture order, and the ITC notifies the Secretary of the Treasury of the issuance of such order, Customs will notify all ports of entry of the order and identify both the article subject to the order and the owners, importers or consignees who are subject to the order.

These seizure orders would be issued by the ITC against specific importers, or their agents and consignees, and would apply only to articles and like articles which have been denied entry by reason of an exclusion order, and for which the importer has been notified in writing.

The amendment also contains procedures that are to be followed by parties having an interest in articles which are seized pursuant to ITC seizure orders and who wish to file a petition for relief.

Regulatory Flexibility Act

For the reasons set forth in the preamble, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendment will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12866

This amendment does not meet the criteria for a "significant regulatory action" as specified in E.O. 12866.

Drafting Information

The principal author of this document was Peter T. Lynch, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 12

Customs duties and inspection, Imports.

Amendment to the Regulations

Accordingly, part 12, Customs Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

1. The general and relevant specific authority citations for part 12 continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Section 12.39 also issued under 19 U.S.C. 1337, 1623;

* * * * *

2. Section 12.39 is amended by revising the heading of paragraph (b); by adding a new paragraph (b)(4); by redesignating paragraphs (c) and (d) as paragraphs (d) and (e); and by adding a new paragraph (c) to read as follows:

§ 12.39 Imported articles involving unfair methods of competition or practices.

* * * * *

(b) *Exclusion from entry; entry under bond; notice of exclusion order.* * * *

(4) In addition to the notice given to importers or consignees of articles released under bond, port directors shall provide written notice to all owners, importers or consignees of articles which are denied entry into the United States pursuant to an exclusion order that any future attempt to import such articles may result in the articles being seized and forfeited. Copies of all such notices are to be forwarded to the Commercial Enforcement, Trade Compliance Division, at Customs Headquarters, and to the Office of The General Counsel, USITC, 500 E Street, SW., Washington, DC 20436 by the district directors.

(c) *Seizure and Forfeiture Orders.* (1) In addition to issuing an exclusion order under paragraph (b)(1) of this section, the Commission may issue an order providing that any article determined to be in violation of § 337 be seized and forfeited to the United States. Such order may be issued if:

(i) The owner, importer, or consignee of the article previously attempted to import the article or like articles into the United States;

(ii) The article or like articles were previously denied entry into the United States by reason of an exclusion order issued under paragraph (b)(1) of this section; and

(iii) Upon such previous denial of entry, the port director of the port in which the entry was attempted had notified the owner, importer, or consignee of the article in writing of both the exclusion order and that seizure and forfeiture would result from any further attempt to import the article or like articles into the United States.

(2) Upon receipt of any seizure order issued by the Commission in accordance with this paragraph, Customs shall immediately notify all ports of entry of the property subject to the seizure order and identify the persons notified under paragraph (b)(4) of this section.

(3) The port director in the port in which the article was seized shall issue a notice of seizure to parties known to have an interest in the seized property. All interested parties to the property shall have an opportunity to petition for relief under the provisions of 19 CFR part 171. All petitions must be filed within 30 days of the date of issuance of the notice of seizure, and failure of a claimant to petition will result in the commencement of administrative forfeiture proceedings. All petitions will be decided by the appropriate Customs officer, based upon the value of the articles under seizure.

(4) If seized articles are found to be not includable in an order for seizure and forfeiture, then the seizure and the forfeiture shall be remitted in accordance with standard Customs procedures.

(5) Forfeited merchandise shall be disposed of in accordance with the Customs laws.

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George J. Weise,
Commissioner of Customs.

Approved: October 10, 1995.
John P. Simpson,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 95-26718 Filed 10-26-95; 8:45 am]
BILLING CODE 4820-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable New Animal Drugs; Flunixin Meglumine Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

EFFECTIVE DATE: October 27, 1995.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1616.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-124, which provides for intravenous or intramuscular use of flunixin meglumine injection for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic in horses.

Approval of ANADA 200-124 for Phoenix Scientific's flunixin meglumine injection is as a generic copy of Banamine® (flunixin meglumine) Injection in Schering-Plough Animal Health's NADA 101-479. The ANADA is approved as of September 25, 1995, and the regulations are amended in § 522.970(b) (21 CFR 522.970(b)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows: