

## Background

Under § 141.4(a), Customs Regulations (19 CFR 141.4(a)), all merchandise imported into the United States is required to be entered, unless specifically excepted. The exceptions from the general rule that all imported merchandise must be entered are set forth in § 141.4(b), Customs Regulations (19 CFR 141.4(b)). In particular, § 141.4(b)(3) excepts instruments of international trade as described in § 10.41a, Customs Regulations (19 CFR 10.41a). In addition to this exemption from entry, however, certain reusable shipping devices arriving from Canada or Mexico are also exempted from entry pursuant to § 10.41b(b), Customs Regulations (19 CFR 10.41b(b)), as amended by Treasury Decision (T.D.) 96-20 (61 FR 7987) of March 1, 1996.

Accordingly, this document amends § 141.4(b)(3), Customs Regulations (19 CFR 141.4(b)(3)), to include a reference to § 10.41b(b), in order to reflect that reusable shipping devices from Canada or Mexico are also exempted from Customs entry requirements. Furthermore, a reference is added in § 141.4(b)(3) to Chapter 98, Subchapter III, U.S. Note 3, Harmonized Tariff Schedule of the United States (HTSUS), which provides the underlying legal authority for the exemption of the specified shipping devices from Customs entry requirements.

## Administrative Procedure Act, the Regulatory Flexibility Act and Executive Order 12866

Because the amendments merely conform with existing law or regulation, notice and public procedure are unnecessary, and for the same reason, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required. Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. Nor do these amendments 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, 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 141

Customs duties and inspection, Entry of merchandise, Release of merchandise, Reporting and recordkeeping requirements.

## Amendment to the Regulation

Part 141, Customs Regulations (19 CFR 141) is amended as set forth below.

### PART 141—ENTRY OF MERCHANDISE

1. The general authority citation for Part 141, Customs Regulations, continues to read, and the specific sectional authority for § 141.4 is revised to read, as follows:

**Authority:** 19 U.S.C. 66, 1448, 1484, 1624.

\* \* \* \* \*

Section 141.4 also issued under 19 U.S.C 1202 (General Note 19; Chapter 86, Additional U.S. Note 1; Chapter 89, Additional U.S. Note 1; Chapter 98, Subchapter III, U.S. Notes 3 and 4; Harmonized Tariff Schedule of the United States), 1498;

\* \* \* \* \*

2. Section 141.4 is amended by revising paragraph (b)(3) to read as follows:

#### § 141.4 Entry required.

\* \* \* \* \*

##### (b) *Exceptions.*

\* \* \*

(3) Instruments of international traffic described in § 10.41a and § 10.41b(b) of this chapter, under the conditions provided for in those sections. See also Chapter 98, Subpart III, U.S. Notes 3 and 4, HTSUS.

\* \* \* \* \*

**Robert C. Bonner,**

*Commissioner of Customs.*

Approved: May 17, 2002.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Decoquinatone and Chlortetracycline

**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 a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved decoquinatone and

chlortetracycline Type A medicated articles to make two-way combination Type B and Type C medicated feeds for calves, beef, and nonlactating dairy cattle used for prevention of coccidiosis, treatment of bacterial enteritis, and treatment of bacterial pneumonia.

**DATES:** This rule is effective May 23, 2002.

#### FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: [jmessenh@cvm.fda.gov](mailto:jmessenh@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-185 that provides for use of DECCOX (decoquinatone) and AUREOMYCIN (chlortetracycline) Type A medicated articles to make combination drug Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle. The combination Type C feeds are used for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for treatment of bacterial enteritis caused by *Escherichia coli*, and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline. The NADA is approved as of March 15, 2002, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of each application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(2) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

**§ 558.195 [Amended]**

2. Section 558.195 *Decoquinat* is amended in the table in paragraph (d) in the entry for the combination “Chlortetracycline approximately 400” in the “Limitations” column by removing “Withdraw 24 hours prior to slaughter.” and by adding in its place “Withdraw 24 hours prior to slaughter when manufactured from CTC (chlortetracycline) Type A medicated articles under NADA 141–147. Zero withdrawal time when manufactured from AUREOMYCIN (chlortetracycline) Type A medicated articles under NADA 141–185.”.

Dated: May 9, 2002.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 165**

**[COTP TAMPA–02–022]**

**RIN 2115–AA97**

**Security Zones; Port of St. Petersburg, St. Petersburg, FL**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary fixed security zones encompassing all waters around all Coast Guard and waterfront facilities and moorings in St. Petersburg Harbor, St. Petersburg, Florida. These security zones are needed for national security reasons to protect Coast Guard vessels and facilities from potential subversive acts. Entry into these zones is prohibited, unless specifically authorized by the Captain of the Port, Tampa, Florida or his designated representative.

**DATES:** This rule is effective from 7 a.m. on May 1, 2002, until 6 p.m. on June 15, 2002.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of [COTP Tampa 02–022] and are available for inspection or copying at Marine Safety Office Tampa, 155 Columbia Drive, Tampa, Florida 33606–3598 between 7:30 a.m. and 3 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LT David G. McClellan, Coast Guard Marine Safety Office Tampa, at (813) 228–2189 extension 102.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing a NPRM and delaying the rule’s effective date would be contrary to the public interest since immediate action is needed to protect the public, ports and waterways of the United States. The Coast Guard will issue a broadcast notice to mariners and place Coast Guard or other law enforcement vessels in the vicinity of these zones to advise mariners of the restriction.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

**Background and Purpose**

Based on the September 11, 2001, terrorist attacks on the World Trade Center buildings in New York and the Pentagon in Arlington, Virginia, there is an increased risk that subversive activity could be launched by vessels or persons in close proximity to Coast Guard Group St. Petersburg or the Army National Guard Base in St. Petersburg Harbor, St. Petersburg, Florida. These security zones will encompass all waters on the north side of channel serving St. Petersburg Harbor, commencing at dayboard “10” in approximate position 27°45.58’ N, 082°37.52’ W, and westward along the seawall 100 feet from the seawall and around all moorings and vessels to the end of the storage facility in approximate position 27°45.68’ N, 082°37.80’ W. The zones will also include the Coast Guard south moorings in St. Petersburg Harbor. This zone will extend 100 feet around the piers commencing from approximate position 27°45.52’ N, 082°37.96’ W to 27°45.52’ N, 082°37.60’ W. All positions noted are fixed using the North American Datum of 1983 (World Geodetic System 1984).

The southern boundary of the zone is shoreward of a line between Green Daybeacon 11 (LLN 2500) westerly to the entrance to Salt Creek. Entry into this security zone is prohibited, unless specifically authorized by the Captain of the Port, Tampa, Florida or his designated representative.

**Regulatory Evaluation**

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. The Office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979).

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard considered whether this rule would have a significant economic effect upon a substantial number of small entities. “Small entities” include small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities because small entities may be allowed to enter on a case by case basis with the authorization of the Captain of the Port.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you