

collection of information requirements subject to review and approval by the Office of Management and Budget (“OMB”) under the Paperwork Reduction Act of 1995. Collection activities are currently approved by the OMB under control number 0625–0037.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information unless it displays a currently valid OMB control number.

*Executive Order 12866.* It has been determined that this rulemaking is not significant for purposes of Executive Order 12866.

*Signing Authority.* With respect to the responsibility of the Department of the Treasury in issuing these joint regulations of the Commerce and Treasury Departments, it is noted that the Secretary of the Treasury retains the sole authority to approve regulation relating to certain customs revenue functions pursuant to 19 CFR 0.1(a)(1). Accordingly, this document is being signed by the Secretary of the Treasury (or his/her delegate), and by the Commissioner of CBP, who is signing this document as the delegate of the Secretary of the Department of Homeland Security.

#### List of Subjects in 15 CFR Part 301

Administrative practice and procedure, Customs duties and inspection, Educational facilities, Imports, Nonprofit organizations, Scientific equipment.

#### Amendments to the Regulations

■ For the reasons set forth in the preamble, part 301 of title 15 of the CFR (15 CFR Part 301) is amended as follows:

#### PART 301—[AMENDED]

■ 1. The authority citation for part 301 is amended to read as follows:

**Authority:** Sec. 6(c), Pub. L. 89–651, 80 Stat. 897, 899; Sec. 2402, Pub. L. 106–36, 113 Stat. 127, 168; 19 U.S.C. 1514(c)(3); and Presidential Proclamation 7011, signed on June 30, 1997.

#### § 301.1 [Amended]

■ 2. Section 301.1 is amended by removing “Secretary of the Treasury (U.S. Customs Service)” in paragraph (c)(2) and adding “Customs and Border Protection” in its place.

#### § 301.2 [Amended]

■ 3. Section 301.2 is amended as follows:

■ a. Paragraph (b) is amended by removing “Customs means the U.S.

Customs Service and “The Commissioner” means Commissioner of the U.S. Customs Service” and adding “The Commissioner means Commissioner of Customs and Border Protection” in its place;

■ b. Paragraph (c) is amended by removing “Customs Port” and adding “CBP Port” in its place;

■ c. The third sentence of paragraph (j) is amended by removing “automatic sampling equipment sold for use with a variety of mass spectrometers” and adding “a vacuum evaporator sold for use with an electron microscope” in its place;

■ d. Paragraph (o) is amended by removing “mass spectrometer” and “x-ray spectrometer”.

#### § 301.3 [Amended]

■ 4. Section 301.3 is amended as follows:

■ a. The first sentence of paragraph (b) is amended by removing “20230, or” and adding “20230, the Web site at <http://ia.ita.doc.gov/sips/index.html>, or” in its place;

■ b. Paragraph (c) is amended by removing the words “U.S. Customs Service, Department of the Treasury,” and adding “U.S. Customs and Border Protection” in its place.

■ 5. Section 301.8 is amended as follows:

■ a. Paragraph (a)(4) is revised;

■ b. The second sentence of paragraph (c) is amended by removing “, within 90 days after notice of liquidation”.

The revision reads as follows:

#### § 301.8 Instructions for entering instruments through U.S. Customs and Border Protection under subheading 9810.00.60, HTSUS.

\* \* \* \* \*

(a) \* \* \*

(4) If a claim for duty-free entry under subheading 9810.00.60, HTSUS is made but is not accompanied by a copy of the properly stamped form, a deposit of the estimated duty is required. Before the entry is liquidated, the applicant must file with the CBP Port a properly stamped copy of the application form. In the event that the CBP Port does not receive a copy of the properly stamped application form before liquidation, the instrument shall be classified and liquidated in the ordinary course, without regard for subheading 9810.00.60, HTSUS.

\* \* \* \* \*

#### §§ 301.1, 301.2, 301.4, 301.5, 301.8, 301.9, 301.10 [Amended]

■ 6. In addition to the amendments set forth above, 15 CFR Part 301 is amended by removing “U.S. Customs Service”,

“U.S. Customs”, or “Customs” and adding “Customs and Border Protection” in its place in the following places:

■ a. Second sentence in § 301.1(d);

■ b. Fourth sentence in § 301.2(k);

■ c. Section 301.4 heading, and first sentence of § 301.4(a) introductory text;

■ d. Second sentence in § 301.5(d)(1)(ii);

■ e. Section 301.8 heading, § 301.8(a)(3), (b) heading and first and second sentences, and (d) first and second sentences;

■ f. Section § 301.9(b) and § 301.9(c); and

■ g. Second sentence in § 301.10(a).

#### §§ 301.7, 301.8, 301.9 [Amended]

■ 7. In addition to the amendments set forth above, 15 CFR Part 301 is amended by removing “Customs Port” and adding “CBP Port” in its place in the following places:

■ a. First sentence in § 301.7(b); and

■ b. Third sentence of § 301.9(a) introductory text.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary for Import Administration, Department of Commerce.*

**Jayson P. Ahern,**

*Acting Commissioner, U.S. Customs and Border Protection, Department of Homeland Security.*

**Timothy Skud,**

*Deputy Assistant Secretary, Department of the Treasury.*

[FR Doc. E9–14884 Filed 6–25–09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

[Docket No. FDA–2009–N–0665]

#### Oral Dosage Form New Animal Drugs; Trilostane

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the supplemental approval of a new animal drug application (NADA) filed by Dechra, Ltd. The supplemental NADA provides for the addition of a 10-milligram capsule size of trilostane, used in dogs for treatment of hyperadrenocorticism.

**DATES:** This rule is effective June 26, 2009.

**FOR FURTHER INFORMATION CONTACT:**

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, filed a supplement to NADA 141-291 that provides for use of VETORYL (trilostane) Capsules in dogs for treatment of pituitary-dependent hyperadrenocorticism and for treatment of hyperadrenocorticism due to adrenocortical tumors. The supplement provides for the use of a 10-milligram capsule size. The supplemental NADA is approved as of June 5, 2009, and the regulations are amended in 21 CFR 520.2598 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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.

The agency has determined under 21 CFR 25.33 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 520**

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 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

**§ 520.2598 [Amended]**

■ 2. In paragraph (a) of § 520.2598 remove "30 or 60 milligrams" and in its place add "10, 30, or 60 milligrams".

Dated: June 19, 2009.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. E9-15152 Filed 6-25-09; 8:45 am]

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**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket No. USCG-2009-0405]

RIN 1625-AA00

**Safety Zone; Harborfest 2009, Parade of Sail, Elizabeth River, Norfolk, VA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a mobile safety zone on the Elizabeth River in the vicinity of Sewell's Point, Virginia, to Town Point Park, Norfolk, Virginia, in support of the Parade of Sail event taking place in conjunction with Harborfest 2009. This action is intended to restrict vessel traffic on the Elizabeth River to protect mariners from the hazards associated with marine parade events.

**DATES:** This rule is effective from 10 a.m. July 3, 2009 through 3 p.m. on July 5, 2009.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0405 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2009-0405 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying at the following location: the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or e-mail LT Tiffany Duffy, Chief, Waterways Management Division, Coast Guard; telephone 757-668-5580, e-mail [Tiffany.A.Duffy@uscg.mil](mailto:Tiffany.A.Duffy@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters.

Additionally, this temporary safety zone will be enforced for approximately 4 hours on Friday, July 3, 2009 and for approximately 4 hours on Sunday, July 5, 2009 while the Parade of Sail arrives at and departs Town Point Park. This safety zone should have a minimal impact on vessel transits because mariners are not precluded from using any portion of the waterway except the safety zone area.

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** as any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters.

**Background and Purpose**

During the period of July 3 through July 5, 2009, the City of Norfolk and Norfolk Festevents Ltd. will sponsor Harborfest 2009, which includes the Parade of Sail event. This event will include a parade of more than twenty ships from around the world departing from Sewell's Point, Virginia enroute to Town Point Park, Norfolk, Virginia on July 3, 2009. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of spectators and transiting vessels. The Coast Guard anticipates numerous spectator craft for these scheduled events. Operators should expect significant vessel congestion along the parade route and viewing areas. The purpose of this regulation is to promote maritime safety and protect participants and the boating public in