Intellectual Property Rights Branch (202) 572–8701; (Operational Aspects) Michael Craig, Office of Field Operations (202) 927–0370.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the provisions of the 1970 UNESCO Convention, codified into U.S. law as the Convention on Cultural Property Implementation Act (Pub. L. 97–446, 19 U.S.C. 2601, *et seq.*) (the Act), the United States, after a request was made by the Government of Cyprus on September 4, 1998, imposed emergency import restrictions on Byzantine ecclesiastical and ritual ethnological material from Cyprus for a period of 5 years from the date of the request. These restrictions and the list of materials covered by them were published in the **Federal Register** (64 FR 17529, April 12, 1999) by the U.S. Customs Service in Treasury Decision (T.D.) 99–35. The T.D. amended § 12.104g(b) of the Customs Regulations which lists emergency import restrictions on cultural property imposed under the Act. The restrictions became effective on April 12, 1999.

Under 19 U.S.C. 2603(c)(3), emergency restrictions may be extended for a period of 3 years upon a determination by the United States that the emergency condition continues to apply with respect to the articles covered by the restrictions. On August 25, 2003, the Acting Assistant Secretary for Educational and Cultural Affairs, Department of State, issued the determination that the emergency condition continues to apply to the articles covered in T.D. 99–35. Accordingly, Customs and Border Protection is amending § 12.104g(b) to reflect the extension of the emergency import restrictions for a 3-year period; this extension of restrictions commences on September 4, 2003. The list of ethnological materials contained in T.D. 99–35 and an accompanying image database may also be found at the following Internet website address: *http://exchanges.state.gov/culprop.*

Based on the foregoing, importation of these materials continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met. For example, these materials may be permitted entry if accompanied by appropriate export certification issued by the Government of Cyprus or by documentation showing that exportation from Cyprus occurred before April 12, 1999.

The document also amends 19 CFR 12.104g(a) and 104g(b), in the third column heading of the lists set forth in those sections, by removing the words ''T.D. No.'' and replacing them with the words ''Decision No.'' This change is made in recognition of the fact that import restrictions are now published by CBP Decisions as opposed to Treasury Decisions. A conforming change is also made to the text of 19 CFR 12.104g(b).

This amendment to the regulations is being issued in accordance with § 0.2(a) of the Customs Regulations (19 CFR 0.2(a)) pertaining to the authority of the Secretary of Homeland Security (or his/her delegate) to prescribe regulations not involving customs revenue functions in accordance with the delegation of such authority by the Secretary of the Treasury.

Inapplicability of Notice and Delayed Effective Date

Because the amendment to the Customs Regulations contained in this document extends emergency import restrictions already imposed on the referenced cultural property of Cyprus under the terms of the Convention on Cultural Property Implementation Act (Pub. L. 97–446, 19 U.S.C. 2601 *et seq.*), in accordance with the 1970 UNESCO Convention and in furtherance of a foreign affairs function of the United States, pursuant to the Administrative Procedure Act (5 U.S.C. 553(a)(1)), no notice of proposed rulemaking or public procedure is necessary and a delayed effective date is not required.

Regulatory Flexibility Act

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. Accordingly, this final rule 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 of a ''significant regulatory action'' as described in E.O. 12866.

Drafting Information

The principal author of this document was Bill Conrad, Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection.

List of Subjects in 19 CFR Part 12

Customs duties and inspections, Imports, Cultural property.

Amendment to the Regulations

■ Accordingly, Part 12 of the Customs Regulations (19 CFR Part 12) is amended, as set forth below:

PART 12—[AMENDED]

■ 1. The general authority and specific authority citations for Part 12, in part, continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

§ 12.104g [Amended]

■ 2. Section 12.104g is amended as follows:

■ a. In paragraph (a), in the heading of column three of the chart, by removing the words ''T.D. No.'' and adding in their place the words ''Decision No.'';

■ b. In paragraph (b), in the second sentence, by removing the words ''Treasury Decision'' and adding in their place the word ''decision'';

■ c. In paragraph (b), in the heading of column three of the chart, by removing the words ''T.D. No.'' and adding in their place the words ''Decision No.''; and

■ d. In paragraph (b), in the third column of the chart relative to the entry for Cyprus, by removing the citation ''99–35'' and adding in its place ''T.D. 99–35 extended by CBP Dec. 03–25''.

Dated: August 26, 2003.

Robert C. Bonner,

Commissioner, Customs and Border Protection.

[FR Doc. 03–22137 Filed 8–28–03; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Tablets; Milbemycin Oxime and Lufenuron Tablets; Nitenpyram Tablets

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 two original new animal drug applications (NADAs) and three supplemental NADAs filed by Novartis Animal Health US, Inc. The original NADAs provide for the concurrent oral use in dogs of approved milbemycin oxime and lufenuron flavor tablets with nitenpyram tablets to kill adult fleas and

prevent flea eggs from hatching and for the concurrent oral use in dogs and cats of approved lufenuron flavor tablets with nitenpyram tablets to kill adult fleas and prevent flea eggs from hatching. The supplemental NADAs provide appropriate labeling for the concurrent uses of the individual products and, for lufenuron flavor tablets, use in puppies and kittens as young as 4 weeks of age.

DATES: This rule is effective August 29, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540; e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141–204 for the concurrent use in dogs of their SENTINEL (milbemycin oxime and lufenuron) FLAVOR TABS, approved under NADA 141–084, with their CAPSTAR (nitenpyram) Tablets, approved under NADA 141–175, to kill adult fleas and prevent flea eggs from hatching. Novartis Animal Health US also filed NADA 141–205 for the concurrent use in dogs and cats of their PROGRAM (lufenuron) FLAVOR TABS, approved under NADA 141–035, with CAPSTAR Tablets to kill adult fleas and prevent flea eggs from hatching. Supplemental NADAs were also filed to NADA 141–035, NADA 141–084, and NADA 141–175 to provide appropriate labeling for the concurrent uses of these products under NADA 141–204 and NADA 141–205, and to NADA 141–035 for use of lufenuron flavor tablets in puppies and kittens as young as four weeks of age. The NADAs and supplemental NADAs are approved as of, June 11, 2003, and the regulations are amended in 21 CFR 520.1288, 520.1446, and 520.1510 to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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.

Under sections 512(c)(2)(F)(ii) or (iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii) or (iii)), these NADAs and supplemental NADAs qualify for 3 years of marketing exclusivity beginning Jue 11, 2003.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are 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.

■ 2. Section 520.1288 is revised to read as follows:

§ 520.1288 Lufenuron tablets.

(a) *Specifications*—(1) Tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) Flavored tablets containing 45, 90, 204.9, or 409.8 milligrams (mg) lufenuron for use as in paragraphs (c)(1)(i), (c)(1)(ii)(A) or (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(3) Flavored tablets containing 90 or 204.9 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A) or (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(4) Flavored tablets containing 135 or 270 mg lufenuron for use as in paragraphs (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Minimum of 10 mg lufenuron per kilogram (4.5 mg per pound (lb)) of body weight, once a month.

(ii) *Indications for use*—(A) For the prevention and control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in dogs and puppies 4 weeks of age and older.

(2) *Cats*—(i) *Amount.* Minimum of 30 mg lufenuron per kilogram (13.6 mg/lb) of body weight, once a month.

(ii) *Indications for use*—(A) For the control of flea populations.

(B) The concurrent use of flavored lufenuron tablets described in paragraph (a)(3) of this section as in paragraph (c)(2)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* For use in cats and kittens 4 weeks of age and older.

■ 3. Section 520.1446 is amended by revising the section heading, paragraphs (a), (d)(1)(i), (d)(1)(ii), and (d)(1)(iii) to read as follows:

§ 520.1446 Milbemycin oxime and lufenuron tablets.

(a) *Specifications*—(1) Tablets containing: 2.3 milligrams (mg) milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

(2) Flavored tablets containing: 2.3 mg milbemycin oxime and 46 mg lufenuron, 5.75 mg milbemycin oxime and 115 mg lufenuron, 11.5 mg milbemycin oxime and 230 mg lufenuron, or 23 mg milbemycin oxime and 460 mg lufenuron.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 0.5 mg milbemycin oxime and 10 mg lufenuron per kilogram of body weight, once a month.

(ii) *Indications for use*—(A) For use in dogs and puppies for the prevention of heartworm disease caused by *Dirofilaria immitis*, for prevention and control of flea populations, for control of adult *Ancylostoma caninum* (hookworm), and for removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm), and *Trichuris vulpis* (whipworm) infections.

(B) The concurrent use of flavored milbemycin oxime and lufenuron tablets described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii)(A) of this section with nitenpyram tablets as in § 520.1510(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 4. Section 520.1510 is revised to read as follows:

§ 520.1510 Nitenpyram tablets.

(a) *Specifications.* Each tablet contains 11.4 or 57 milligrams (mg) nitenpyram.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Special considerations.* The concurrent use of nitenpyram tablets and flavored milbemycin/lufenuron tablets as in paragraph (d)(1)(ii)(B) of this section shall be by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) One 11.4-mg tablet for dogs weighing less than 25 pounds (lb) or one 57-mg tablet for dogs weighing more than 25 lb, as needed, for use as in paragraph (d)(1)(ii)(A) of this section.

(B) One 11.4-mg tablet for dogs weighing less than 25 lb or one 57 mg tablet for dogs weighing more than 25 lbs, once or twice weekly, for use as in paragraph (d)(1)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

Dated: August 18, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–22072 Filed 8–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–03–125]

RIN 1625–AA08

Special Local Regulations for Marine Events; Hampton River, Hampton, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of implementation of regulation.

SUMMARY: The Coast Guard is implementing the special local regulations at 33 CFR 100.508 during the Hampton Bay Days Festival to be held September 5–7, 2003, on the waters of the Hampton River at Hampton, Virginia. These special local regulations are necessary to control vessel traffic due to the confined nature of the waterway and expected vessel congestion during the festival events. The effect will be to restrict general navigation in the regulated area for the safety of event participants, spectators and vessels transiting the event area.

EFFECTIVE DATES: 33 CFR 100.508 is effective from 12 noon on September 5, 2003 to 6 p.m. on September 7, 2003.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer J. Saffold, Marine Events Coordinator, Commander, Coast Guard Group Hampton Roads, 4000 Coast Guard Blvd., Portsmouth, VA 23703–2199, (757) 483–8521.

SUPPLEMENTARY INFORMATION: Hampton Bay Days, Inc. will sponsor the Hampton Bay Days Festival on September 5–7, 2003 on the Hampton River, Hampton, Virginia. The festival will include water ski demonstrations, personal watercraft and wake board competitions, paddle boat races, classic boat displays, fireworks displays and a helicopter rescue demonstration. A fleet of spectator vessels is expected to gather nearby to view the festival events. In order to ensure the safety of participants, spectators and transiting vessels, 33 CFR 100.508 will be in effect for the duration of the festival activities. Under provisions of 33 CFR 100.508, vessels may not enter the regulated area without permission from the Coast Guard Patrol Commander. Spectator vessels may enter and anchor in the special spectator anchorage areas if they proceed at slow, no wake speed. The Coast Guard Patrol Commander will allow vessels to transit the regulated area between festival events. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

In addition to this notice, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Dated: August 20, 2003.

Ben R. Thomason, III,

Captain, U.S. Coast Guard, Acting Commander, Fifth Coast Guard District.

[FR Doc. 03–22136 Filed 8–28–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WI–113–3; FRL–7528–7]

Approval and Promulgation of State Implementation Plans; Wisconsin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is approving a revision to Wisconsin's State Implementation Plan (SIP) for the attainment of the one-hour ozone standard for the Milwaukee-Racine area. This SIP revision, submitted to EPA on December 16, 2002, allows emissions averaging for sources subject to the state's rules limiting emissions of nitrogen oxides (NO_X) from large electricity generating units in southeast Wisconsin. In addition, the revision creates a new categorical emissions limit for new integrated gasification combined cycle units. On April 10, 2003, the EPA proposed approval of this SIP revision and published a direct final approval as well. EPA received adverse comments on the proposed rulemaking, and therefore withdrew the direct final rulemaking on June 6, 2003.

DATES: This final rule is effective September 29, 2003.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the following address: U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. We recommend that you telephone Alexis Cain at (312) 886–7018 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Alexis Cain, Environmental Scientist, Regulation Development Section, Air Programs Branch (AR–18J), USEPA,