

# Rules and Regulations

Federal Register

Vol. 68, No. 98

Wednesday, May 21, 2003

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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; Bambermycins

**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 supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for use of bambermycins Type A medicated articles to make Type B and Type C medicated feeds used to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when consumed free-choice or hand-fed at a rate of not less than 10 milligrams (mg) nor more than 40 mg bambermycins per head per day.

**DATES:** This rule is effective May 21, 2003.

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: [edubbin@cvm.fda.gov](mailto:edubbin@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., PO Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 141-034 that provides for use of GAINPRO (bambermycins) Type A medicated articles to make Type B and Type C medicated feeds used to increase rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers) when consumed free-choice or hand-fed at a rate of not less than 10 mg nor more than 40 mg bambermycins per head per

day. The supplemental NADA is approved as of February 10, 2003, and the regulations are amended in 21 CFR 558.95 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 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

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.

#### § 558.95 [Amended]

■ 2. Section 558.95 *Bambermycins* is amended by:

- a. In paragraphs (d)(4)(ii)(b) and (d)(4)(iv)(a) by removing "20" and by adding in its place "40";
- b. In paragraph (d)(4)(iii)(d) by adding "cattle, and dairy and beef replacement heifers" after "feeder", and by removing

"5.33" and "10- to 20-milligrams" and by adding in their respective places "10.66" and "10 to 40 milligrams"; and

■ c. In paragraphs (d)(4)(ii)(b), (d)(4)(iii)(d), and (d)(4)(iv)(c) by adding "Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day." at the end of the paragraph.

Dated: May 8, 2003.

**Steven D. Vaughn,**

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

[FR Doc. 03-12721 Filed 5-20-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD09-03-214]

RIN 1625-AA11

#### Regulated Navigation Area; Des Plaines River, Joliet, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule; request for comments.

**SUMMARY:** The Coast Guard is establishing a regulated navigation area on the Des Plaines River in Joliet, Illinois. This temporary final rule requires that certain southbound tows passing under the Jefferson Street bridge use an assist tug. This action is necessary to ensure vessel and public safety due to an allision with this bridge structure. This rule is intended to restrict vessel traffic in a portion of the Des Plaines River near Joliet, Illinois.

**DATES:** This rule is effective from 8 a.m. (local) on May 11, 2003 until November 15, 2003.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket [CGD09-02-214] and are available for inspection or copying at Coast Guard Marine Safety Office (MSO) Chicago, 215 W. 83rd St, Suite D, Burr Ridge, Illinois 60521 between 8 a.m. and 3:30 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** MST2 Kenneth Brockhouse, U.S. Coast Guard Marine Safety Office Chicago, at (630) 986-2175.

**SUPPLEMENTARY INFORMATION:****Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related material. We encourage comments on whether a regulated navigation area is the appropriate tool to provide for the safe navigation of tows transiting through the draws of the Jefferson Street bridge on the Des Plaines River in the vicinity of Joliet, Illinois. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD09-03-214), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

**Public Meeting**

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Marine Safety Office Chicago at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

**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 an NPRM, and under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. On May 2, 2003, a tow allided with the pier of the Jefferson Street Bridge which resulted in substantial damage to the bridge structure. As a result, it is estimated that the bridge will be inoperable for 4 to 6 months while repairs are made. The Captain of the Port Chicago believes that immediate action is necessary to help prevent any future allisions with the pier. Further, additional allisions might result in total structural failure, closure of the river for a period of time as a result of an allision, and the possible loss of life as a result of another allision.

**Background and Purpose**

On May 2, 2003, a southbound tow allided with the pier of the Jefferson Street bridge. This allision resulted in significant structural damage to the bridge pier. Southbound tows with a 3 by 5 configuration, transiting under the Cass Street Bridge and then the Jefferson Street Bridge, only have 100 feet of horizontal maneuvering room. In addition, the Des Plaines River regularly has significant current in this area.

In order to prevent future allisions, a regulated navigation area (RNA) is being established from the Ruby Street Bridge to the McDonough Street Bridge in which southbound tows in a 3 by 5 configuration must use an assist tug. This RNA is being established until an adequate protection cell is constructed around the bridge pier.

**Discussion of Rule**

Southbound tows greater than 89 feet in overall width and more than 800 feet in length must use an assist tug when transiting through the RNA. This RNA encompasses the Des Plaines River from mile 288.7 (the Ruby Street Bridge), to mile 287.3 (the McDonough Street Bridge). Deviation from this rule is prohibited unless specifically authorized by the Commander, Ninth Coast Guard District or his designated representative. His designated representative is the Captain of the Port Chicago.

**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 Homeland Security. The operational reporting requirements of the RNA are minimal and necessary to provide immediate, improved security for the public, vessels, and U.S. ports and waterways. The requirements do not alter normal barge cargo loading operations or transits. Additionally, this rule is temporary in nature and the Coast Guard may issue a NPRM as it considers whether to make this rule permanent. The minimal hardships that may be experienced by persons or vessels are necessary to the national interest in protecting the public, vessels, and vessel crews from the devastating consequences of acts of terrorism, and from sabotage or other subversive acts,

accidents, or other causes of a similar nature.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises 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. This rule will affect the following entities, some of which may be small entities: The operators of southbound tows, in a 3 by 5 configuration, intending to transit through the RNA. This RNA will not have a significant economic impact on a substantial number of small entities because this rule will only remain in effect until a protection cell can be erected or until other recommendations are provided which reduce the risk of allisions with the Jefferson Street Bridge.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

**Assistance for Small Entities**

Under subsection 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we offered to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. 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 wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

**Collection of Information**

This rule calls for no new collection of information under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520).

### Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

### Environment

We have analyzed this rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1 paragraph (34)(g), of the instruction, from further environmental documentation because this rule is not expected to result in any significant environmental impact as described in NEPA. A final “Environmental Analysis Check List” and a final “Categorical Exclusion Determination” are available in the docket where indicated under ADDRESSES.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Vessels, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.

■ 2. From 8 a.m. on May 11, 2003 through 8 p.m. on November 15, 2003 add temporary § 165.T09–214 to read as follows:

#### § 165.T09–214 Regulated Navigation Area; Des Plaines River, Joliet, Illinois

(a) *Regulated navigation area.* The following waters are a Regulated

Navigation Area (RNA): All portions of the Des Plaines River between mile 287.3 (McDonough St. Bridge) and mile 288.7 (Ruby Street Bridge).

(b) *Applicability.* This section applies to operators of all southbound tows transiting beneath the Jefferson Street Bridge (mile 287.9), Joliet, Illinois with barge configurations of over 89 feet in overall width and more than 800 feet in length.

(c) *Regulations.* (1) All southbound tows to which this section applies must use an assist tug when transiting through the RNA.

(2) The general regulations contained in 33 CFR 165.13 apply to this section.

(3) Deviation from this section is prohibited unless specifically authorized by the Commander, Ninth Coast Guard District or his designated representatives. Designated representatives include the Captain of the Port Chicago.

Dated: May 9, 2003.

**Ronald F. Silva,**

*Rear Admiral, Coast Guard, Commander, Ninth Coast Guard District.*

[FR Doc. 03–12687 Filed 5–20–03; 8:45 am]

BILLING CODE 4910–15–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[OPP–2003–0163; FRL–7306–1]

### Pyraflufen-ethyl; Pesticide Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for combined residues of pyraflufen-ethyl in or on cotton.

Nichino America Incorporated requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

**DATES:** This regulation is effective May 21, 2003. Objections and requests for hearings, identified by docket ID number OPP–2003–0163, must be received on or before July 21, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit VI. of the SUPPLEMENTARY INFORMATION.

#### FOR FURTHER INFORMATION CONTACT:

Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,