

MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

AQUAFLO-CA1 in the dosage form and for the intended uses conditionally approved by FDA under application number 141-259 qualifies for 7 years of exclusive marketing rights beginning on the date of approval. This new animal drug qualifies for exclusive marketing rights under section 573(c) of the act (21 U.S.C. 360ccc-2(c)) because it has been declared a designated new animal drug by FDA under section 573(a) of the act.

FDA has determined under 21 CFR 25.33(d)(4) 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

##### 21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

##### 21 CFR Part 556

Animal drugs, Foods.

■ 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 parts 516 and 556 are amended as follows:

#### PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 1. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-2, 371.

■ 2. Add subpart E to read as follows:

#### Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

##### § 516.1215 Florfenicol.

(a) *Specifications.* Type A medicated article containing 500 grams (g) florfenicol per kilogram.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following: "Conditionally approved by FDA pending a full demonstration of effectiveness under application number 141-259. Extra-

label use of this drug in or on animal feed is strictly prohibited."

(d) *Related tolerances.* See § 556.283 of this chapter.

(e) *Conditions of use—(1) Catfish—(i) Amount.* Feed 182 to 1816 g florfenicol per ton of feed as a sole ration for 10 consecutive days to deliver 10 milligrams florfenicol per kilogram of fish.

(ii) *Indications for use.* For the control of mortality due to columnaris disease associated with *Flavobacterium columnare*.

(iii) *Limitations.* Feed containing florfenicol shall not be fed to catfish for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 12 days prior to slaughter. Federal law limits this drug to use under the professional supervision of a licensed veterinarian. The expiration date of veterinary feed directives (VFDs) for florfenicol must not exceed 15 days from the date of prescribing. VFDs for florfenicol shall not be refilled. See § 558.6 of this chapter for additional requirements.

(2) [Reserved]

#### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 4. In § 556.283, revise paragraph (c) to read as follows:

##### § 556.283 Florfenicol.

\* \* \* \* \*

(c) *Related conditions of use.* See §§ 516.1215, 520.955, 522.955, and 558.261 of this chapter.

Dated: September 27, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

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#### DEPARTMENT OF HOMELAND SECURITY

##### Coast Guard

#### 33 CFR Part 165

[COTP MIAMI 07-142]

RIN 1625-AA00

#### Safety Zone; Monthly Biscayne Bay Yacht Racing Association Cruising Races, Biscayne Bay, Miami, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for the Monthly Biscayne Bay Yacht Racing Association (BBYRA) Cruising Races, which will temporarily limit the movement of non-participant vessels in Biscayne Bay near Miami, FL. This temporary safety zone is intended to restrict vessels from entering the waters where the event will be held unless specifically authorized by the Captain of the Port, Miami, Florida or his designated representative. This regulation is needed to protect the safety of participants, marine spectators and recreational and professional mariner traffic.

**DATES:** This rule is effective from 11 a.m. until 4 p.m. each day on Saturday, September 8, 2007 and Sunday, October 14, 2007.

**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 docket COTP MIAMI 07-142 and are available for inspection or copying at Sector Miami, 100 MacArthur Causeway, Miami Beach, FL 33139 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** MSTCS R. Johnson, Coast Guard Sector Miami, Florida, at (305) 535-4317.

#### 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 an NPRM. Notice of these events was not provided to the Coast Guard with sufficient time to publish an NPRM and receive public comment before the event dates. This temporary rule is necessary to ensure the safety of participants, spectators, and the general public from the hazards associated with a boat race.

For the same reasons, the Coast Guard also finds, under 5 U.S.C. (d)(3), that

good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

### **Background and Purpose**

The Biscayne Bay Yacht Racing Association is sponsoring the Monthly BBYRA Cruising Races, and approximately 35 sailboats, 20 to 54 feet in the length, are expected to participate. The event will be held each day from 11 a.m. until 4 p.m. on September 8, 2007 and October 14, 2007. The public is invited to attend. The high concentration of event participants, spectators, and the general boating public presents an extra hazard to the safety of life on the navigable waters of the United States. A temporary safety zone encompassing the waters in Biscayne Bay & the Intracoastal Waterway is necessary to protect participants as well as spectators from hazards associated with the event.

### **Discussion of Rule**

This rule establishes a temporary safety zone for the Monthly BBYRA Cruising Races in Biscayne Bay near Miami, FL. The safety zone is 100 yards around all race participants as they transit the waters of Biscayne Bay south of the Rickenbaucker Causeway to Latitude 25°32'00". Vessels are prohibited from anchoring, mooring, or transiting within these zones, unless authorized by the Captain of the Port, Miami, Florida, or his designated representative. If the Coast Guard Patrol Commander determines that it is safe for vessels to transit the regulated area, vessels may proceed through the regulated area between scheduled racing events. A succession of not fewer than 5 short whistle or horn blasts from a Coast Guard patrol vessel will be the signal for any and all vessels within the regulated area to take immediate steps to avoid collision. Traffic may resume normal operations at the completion of the scheduled races and exhibitions as determined by the Coast Guard Patrol Commander. The temporary safety zone will protect the participants and the public from the dangers associated with the event. This regulation is effective each day from 11 a.m. until 4 p.m. on September 8, 2007 and October 14, 2007.

### **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.

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. Entry into the regulated area is prohibited for only limited time periods, and all vessels should be able to safely transit around the regulated area at all times. If the Coast Guard Patrol Commander determines that it is safe for vessels to transit the regulated area, vessels may proceed through the regulated area between scheduled racing events. Traffic may resume normal operations at the completion of scheduled races and exhibitions as determined by the Coast Guard Patrol Commander. Finally, advance notifications to the maritime community through marine information broadcasts will allow mariners to adjust their plans accordingly.

### **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 owners or operators of vessels intending to transit or anchor in the waters of Biscayne Bay during the effective period. This temporary safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only 5.0 hours during the day, vessel traffic may safely pass around the safety zone, and vessels may pass through the regulated area with the permission of the Coast Guard Patrol Commander.

### **Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they could 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 affect 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.

#### *Technical Standards*

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### *Environment*

We have analyzed this rule under Commandant Instruction M16475.ID, 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 a 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. A final "Environmental Analysis Check List" and a final "Categorical Exclusion Determination" will be 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, 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. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6 and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 165.T07-142 to read as follows:

#### **§ 165.T07-142 Safety Zone: Monthly Biscayne Bay Yacht Racing Association Cruising Races; Biscayne Bay, Miami, FL.**

(a) *Location.* The following area is a safety zone: All waters within 100 yards around all participants in the BBYRA Cruising Races as they transit the waters of Biscayne Bay south of the Rickenbaucker Causeway to Latitude 25°32'00".

(b) *Definition.* The following definition applies to this section:

*Designated representative* is a Coast Guard Patrol Commander, including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the Captain of the Port of Miami in restricting vessels and persons from entering the temporary safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, no person or vessel may anchor, moor or transit a safety zone without permission of the Captain of the Port Sector Miami or his designated representative. To request permission to enter into a safety zone, the designated representative may be contacted on VHF channel 16.

(2) At the completion of scheduled races and exhibitions, and departure of participants from the area, the Coast Guard Patrol Commander may permit traffic to resume normal operations.

(3) Between scheduled events, the Coast Guard Patrol Commander may permit traffic to resume normal operations for a limited time.

(4) A succession of not fewer than 5 short whistle or horn blasts from a Coast Guard patrol vessel will be the signal for any and all vessels within the safety zone defined in paragraph (a) to take immediate steps to avoid collision.

(d) *Effective Dates.* This rule is effective each day from 11 a.m. to 4 p.m. on Saturday, September 8, 2007 and on Sunday, October 14, 2007.

Dated: September 7, 2007.

**K.L. Schultz,**

*Captain, U.S. Coast Guard, Captain of the Port Miami, FL.*

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#### **ENVIRONMENTAL PROTECTION AGENCY**

#### **40 CFR Part 52**

[EPA-R04-OAR-2007-0251-200738; FRL-8478-6]

#### **Approval and Promulgation of Implementation Plans; Georgia; Clean Air Interstate Rule**

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

**ACTION:** Final rule.

**SUMMARY:** EPA is taking final action to approve a revision to the Georgia State Implementation Plan (SIP) submitted on March 28, 2007. This revision addresses the requirements of EPA's Clean Air Interstate Rule (CAIR) promulgated on May 12, 2005, and subsequently revised on April 28, 2006, and December 13, 2006. EPA has determined that the SIP revision fully implements the CAIR requirements for Georgia. As a result of this action, EPA will also withdraw, through a separate rulemaking, the CAIR Federal Implementation Plans (FIPs) concerning sulfur dioxide (SO<sub>2</sub>), and nitrogen oxides (NO<sub>x</sub> annual) season emissions for Georgia. The CAIR FIPs for all States in the CAIR region were promulgated on April 28, 2006, and subsequently revised on December 13, 2006.

CAIR requires States to reduce emissions of SO<sub>2</sub> and NO<sub>x</sub> that significantly contribute to, and interfere with maintenance of, the National Ambient Air Quality Standards (NAAQS) for fine particulates (PM<sub>2.5</sub>) and/or ozone in any downwind state. CAIR establishes State budgets for SO<sub>2</sub> and NO<sub>x</sub> and requires States to submit SIP revisions that implement these