

SUPPLEMENTARY INFORMATION: Alpharma Inc., 440 Route 22, Bridgewater, NJ 08807, filed ANADA 200-441 that provides for the use of A-MYCIN (chlortetracycline) Soluble Powder to make medicated drinking water for cattle, swine, chickens, and turkeys for the treatment of several bacterial diseases. Alpharma Inc.'s A-MYCIN Soluble Powder is approved as a generic copy of Fort Dodge Animal Health, A Division of Wyeth Holdings Corp.'s AUREOMYCIN (chlortetracycline) Soluble Powder, approved under NADA 65-440. The ANADA is approved as of October 9, 2009, and the regulations are amended in 21 CFR 520.445b 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.

FDA 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.

■ 2. In § 520.445b, revise paragraph (b)(2) to read as follows:

§ 520.445b Chlortetracycline powder.

* * * * *

(b) * * *

(2) Nos. 046573 and 053501 for use as in paragraph (d) of this section.

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Dated: November 23, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-28468 Filed 11-27-09; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0985]

RIN 1625-AA00

Safety Zone; Atlantic Intracoastal Waterway, Sunset Beach, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of the Atlantic Intracoastal Waterway at Sunset Beach, North Carolina. The safety zone is necessary to provide for the safety of mariners on navigable waters during the installation of bridge girders at the new high-level fixed highway bridge at Sunset Beach, North Carolina.

DATES: This rule will be in effect from 6 a.m. on December 1, 2009 through 6 p.m. on January 31, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2009-0985 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0985 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at 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 CWO4 Stephen Lyons, Waterways Management Division Chief, Coast Guard Sector North Carolina; telephone (252) 247-4525, e-mail

Stephen.W.Lyons2@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 it is in the public interest to have this regulation in place during the girder installation due to the hazards associated with potential falling debris and the use of heavy equipment and machinery in the waterway.

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**. Delaying the effective date would be contrary to public interest, since immediate action is needed to ensure the public's safety from the hazards noted above.

Background and Purpose

The State of North Carolina Department of Transportation awarded a contract to English Construction Company Inc. of Lynchburg, Virginia to perform bridge girder installation at the new high-level fixed highway bridge at Sunset Beach, North Carolina. The contract provides for the installation of bridge girders. The center bridge girder installation is scheduled daily from 6 a.m. on December 1, 2009 through 6 p.m. on January 31, 2010. The contractor will be utilizing a deck barge with a 50' beam, a ringer crane on a stationary barge with an 85' beam, and an assist tug to conduct the girder installation. This operation presents a potential hazard to mariners from falling debris and the use of heavy equipment and machinery. To provide for the safety of the public, the Coast Guard will temporarily restrict access to this section of the Atlantic Intracoastal Waterway during girder installation, scheduled daily from 6 a.m. until 6 p.m.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone to encompass the waters of the Atlantic Intracoastal Waterway extending 250 yards in all directions from the main construction site. All vessels are prohibited from transiting this section of the waterway while the safety zone is in effect. Entry into the zone will not be permitted except as specifically authorized by the Captain of the Port or a designated

representative. To seek permission to transit the area, mariners can contact Sector North Carolina at telephone number (252) 247-4570. This zone will be enforced daily from 6 a.m. until 6 p.m. while girder installation is in progress from 6 a.m. on December 1, 2009 through 6 p.m. on January 31, 2010.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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.

Although this regulation will restrict access to the area, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration of time, (ii) the Coast Guard will give advance notification via maritime advisories so mariners can adjust their plans accordingly, and (iii) vessels may be granted permission to transit the area by the Captain of the Port or a designated representative.

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 tug and barge, recreational, and fishing vessels intending to transit the specified portion of the Atlantic Intracoastal Waterway from 6 a.m. on December 1, 2009 through 6 p.m. on January 31, 2010.

This safety zone will not have a significant economic impact on a substantial number of small entities for

the following reasons. This rule will be enforced for only a limited time each day. Although the safety zone will apply to the entire width of the Atlantic Intracoastal Waterway, vessel traffic can use alternate waterways to transit safely around the safety zone. Before the effective period, the Coast Guard will issue maritime advisories widely available to the users of the waterway.

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.

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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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, eliminates 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 Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule establishes a temporary safety zone to protect the public from bridge construction operations. An environmental analysis checklist and a 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, Waterways.

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

PART 165—SAFETY ZONES

■ 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, 3306, 3703; 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.T05-0985 to read as follows:

§ 165.T05-0985 Safety Zone; Atlantic Intracoastal Waterway, Sunset Beach, NC.

(a) *Definitions.* For the purposes of this section, Captain of the Port means the Commander, Sector North Carolina. *Representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized to act on the behalf of the Captain of the Port.

(b) *Location.* The following area is a safety zone: This zone includes the waters of the Atlantic Intracoastal Waterway extending 250 yards in all directions from the main construction site at the new high-level fixed highway bridge at Sunset Beach, North Carolina.

(c) *Regulations.* (1) The general regulations contained in § 165.23 of this part apply to the area described in paragraph (b) of this section.

(2) Persons or vessels requiring entry into or passage through any portion of the safety zone must first request authorization from the Captain of the Port, or a designated representative, unless the Captain of the Port previously announced via Marine Safety Radio Broadcast on VHF Marine Band Radio channel 22 (157.1 MHz) that this regulation will not be enforced in that portion of the safety zone. The Captain of the Port can be contacted at telephone number (252) 247-4570 or by radio on VHF Marine Band Radio, channels 13 and 16.

(d) *Enforcement.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the zone by Federal, State, and local agencies.

(e) *Enforcement period.* This section will be enforced daily from 6 a.m. until 6 p.m. throughout the effective period from 6 a.m. on December 1, 2009 through 6 p.m. on January 31, 2010 unless cancelled earlier by the Captain of the Port. The exact daily times will be announced in Broadcast Notice to Mariners.

Dated: November 16, 2009.

J.E. Ryan,

Captain, U.S. Coast Guard, Captain of the Port North Carolina.

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BILLING CODE 9110-04-P

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2010-3 and CP2010-3; Order No. 325]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding Priority Mail Contract 21 to the Competitive Product List. This action is consistent with changes in a recent law governing postal operations. Replication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

DATES: Effective November 30, 2009 and is applicable beginning October 28, 2009.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202-789-6820 or stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION: *Regulatory History*, 74 FR 54599 (October 22, 2009).

I. Introduction
II. Background
III. Comments
IV. Commission Analysis
V. Ordering Paragraphs

I. Introduction

The Postal Service seeks to add a new product identified as Priority Mail Contract 21 to the Competitive Product List. For the reasons discussed below, the Commission approves the Request.

II. Background

On October 14, 2009, the Postal Service filed a formal request pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.* to add Priority Mail Contract 21 to the Competitive Product List.¹ The Postal Service asserts that the Priority Mail Contract 21 product is a competitive product “not of general applicability” within the meaning of 39 U.S.C. 3632(b)(3). This Request has been assigned Docket No. MC2010-3.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010-3.

In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors’ Decision, originally filed in Docket No. MC2009-25, authorizing the Priority Mail Contract Group;² (2) a redacted version of the contract;³ (3) a requested change in the Mail Classification Schedule product list;⁴ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁵ (5) a certification of compliance with 39 U.S.C. 3633(a);⁶ and (6) an application for non-public treatment of the materials filed under seal.⁷ The redacted version of the contract provides that the contract is terminable on 30 days’ notice by either

¹ Request of the United States Postal Service to Add Priority Mail Contract 21 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, October 14, 2009 (Request).

² Attachment A to the Request, reflecting Governors’ Decision No. 09-6, April 27, 2009.

³ Attachment B to the Request.

⁴ Attachment C to the Request.

⁵ Attachment D to the Request.

⁶ Attachment E to the Request.

⁷ Attachment F to the Request.