

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1115 [Amended]

2. Section 529.1115 *Halothane* is amended in paragraph (b) by adding after "000856" the phrase "and 012164".

Dated: May 19, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-14102 Filed 5-28-97; 8:45 am]

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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; Salinomycin, Roxarsone, Bacitracin Methylene Disalicylate

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

Hoffmann-La Roche, Inc. The supplemental NADA provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing salinomycin with roxarsone and bacitracin methylene disalicylate.

EFFECTIVE DATE: May 29, 1997

FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2604.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110-1199,

filed supplemental NADA 135-321 which provides for use of single ingredient Type A medicated articles containing Bio-Cox® (salinomycin as salinomycin sodium) 30 grams-per-pound (g/lb), BMD® (bacitracin methylene disalicylate) 30, 50, 60, or 75 g/lb bacitracin activity, 3-Nitro® (roxarsone) 45.4, 90, or 227 g/lb roxarsone activity, to make Type C broiler chicken feeds containing 40 to 60 g per ton (g/t) salinomycin sodium, 34.1 or 45.4 g/t roxarsone, and 4 to 50 g/t bacitracin methylene disalicylate, for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than salinomycin alone; and for increased rate of weight gain. Use of 34.1 or 45.4 g/t roxarsone is indicated to meet the *E. tenella* challenge, which varies with environmental and management conditions. The supplement is approved as of May 29, 1997. The basis of approval is discussed in the freedom of information summary.

Also, 21 CFR 558.550 is amended to redesignate existing paragraph (b) as paragraph (d) and to add new paragraphs (b) and (c) to provide for more uniform regulations and for future expansion. The regulations are amended in newly redesignated paragraph (d) by adding new paragraph (d)(1)(xvii) to reflect the approval.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), use of salinomycin, roxarsone, and bacitracin methylene disalicylate Type A medicated articles to make Type C medicated feeds as provided in NADA 135-321 is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning May 29, 1997, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new combination providing for a 34.1 g/t level of roxarsone.

The agency has determined under 21 CFR 25.24(d)(1)(ii) 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.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.550 is amended by redesignating paragraph (b) as paragraph (d), by adding and reserving new paragraphs (b) and (c), and by adding new paragraph (d)(1)(xvii) to newly redesignated paragraph (d) to read as follows:

§ 558.550 Salinomycin.

- * * * * *
- (b) [Reserved]
- (c) [Reserved]
- (d) * * *

(1) * * *

(xvii) (A) *Amount per ton.*

Salinomycin 40 to 60 grams with roxarsone 34.1 or 45.4 grams and bacitracin methylene disalicylate 4 to 50 grams.

(B) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; for increased rate of weight gain. Use of 34.1 or 45.4 grams per ton roxarsone is indicated to meet the *E. tenella* challenge which varies with environmental and management conditions.

(C) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Not approved for use with pellet binders. Do not feed to laying chickens. May be fatal if accidentally fed to adult turkeys or horses. Poultry should have access to drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Salinomycin as provided by No. 000004 in § 510.600(c) of this chapter. Roxarsone and bacitracin as provided by No. 046573 in § 510.600(c) of this chapter.

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Dated: May 16, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 97-14106 Filed 5-28-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD 05-97-032]

RIN 2115-AA97

Security Zone; Elizabeth River, Norfolk, VA

AGENCY: Coast Guard, DOT.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is establishing a temporary security zone around the Nauticus National Maritime Center Norfolk, VA. This security zone will prohibit access by all unauthorized persons to all waters within a 100 yard radius from position 36-50.9N, 076-17.8W. The security zone is needed to protect U.S. Coast Guard vessels, staff and participants in the U.S. Coast Guard Maintenance and Logistics Command

Atlantic Area Change of Command ceremony. Entry into this zone is prohibited unless authorized by the Captain of the Port Hampton Roads.

DATES: This regulation is effective from 8 a.m. to 5 p.m. May 30, 1997, unless sooner terminated by the Captain of The Port Hampton Roads.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Janiece Benjamin, Project Officer, USCG Marine Safety Office Hampton Roads, telephone number (757) 441-3299.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a Notice of Proposed Rule Making (NPRM) was not published for this rule and good cause exists for making it effective less than 30 days after **Federal Register** publication. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to protect the vessels and participants involved in the U.S. Coast Guard Maintenance and Logistics Command, Atlantic Area Change of Command Ceremony.

Discussion of the Regulation.

This temporary rule is issued to protect U.S. Coast Guard vessels, staff and participants in the U.S. Coast Guard Maintenance and Logistics Command Atlantic Area Change of Command ceremony being held at the Nauticus National Maritime Center, Norfolk, VA. The Coast Guard is establishing a 100 yard radius security zone around the maritime center's piers while the ceremony is conducted. This security zone will prohibit access by all unauthorized persons to all waters within a 100 yard radius from position 36-50.9N, 076-17.8W. Persons or vessels requiring entry into or passage through the security zone must request authorization from the Captain of the Port.

Regulatory Evaluation

This temporary rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2.e(34) of Commandant Instruction M16475.1B (as revised by 59 FR 38654, July 29, 1994), this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways

Regulation

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

PART 165—[AMENDED]

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.; 49 CFR 1.46.

2. A new temporary § 165.T05-032 is added to read as follows:

§ 165.T05-032 Security Zone: Elizabeth River, Norfolk, Virginia.

(a) *Location:* The following area is a security zone: All waters within a 100 yard radius from position 36-50.9N, 076-17.8W on the Elizabeth River at the Nauticus National Maritime Center, Norfolk, Virginia, during the U.S. Coast Guard Maintenance and Logistics Command Atlantic Area Change of Command Ceremony.

[DATUM NAD 1983]

(b) *Captain of the Port* means the Commanding Officer of the Marine Safety Office Hampton Roads, Norfolk, VA or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(c) (1) In accordance with the general regulations in §§ 165.33 and 165.501 of this part, entry into this zone is prohibited unless authorized by the