

and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

XI. References

1. Golubev, W. I., "Perfect State of *Rhodomyces dendrorhous* (*Phaffia rhodozyma*)," *Yeast*, 11:101-110, 1995.
2. Andrewes, A. G., H. J. Phaff, and M. P. Starr, "Carotenoids of *Phaffia rhodozyma*, a Red-Pigmented Fermenting Yeast," *Phytochemistry*, 15:1003-1007, 1976.
3. Johnson, E. A., D. E. Conklin, and M. J. Lewis, "The Yeast *Phaffia rhodozyma* as a Dietary Pigment Source for Salmonids and Crustaceans," *Journal of the Fishers Research Board of Canada*, 34:2417-2421, 1977.
4. Johnson, C. B., memorandum entitled "Astaxanthin from *Phaffia rhodozyma*: Final Toxicology Review" from the Division of Health Effects Evaluation (HFS-225) to the Division of Petition Control (HFS-215), Center for Food Safety and Applied Nutrition, FDA, August 12, 1999.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. New § 73.355 is added to subpart A to read as follows:

§ 73.355 *Phaffia* yeast.

(a) *Identity.* (1) The color additive *phaffia* yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *Phaffia rhodozyma*.

(2) *Phaffia* yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with *phaffia* yeast may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* *Phaffia* yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Physical state, solid.

Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.

Mercury, not more than 1 part per million.

Heavy metals (as Pb), not more than 10 parts per million.

Astaxanthin, not less than 0.4 percent.

(c) *Uses and restrictions.* *Phaffia* yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of astaxanthin in finished feed, from *phaffia* yeast when used alone or in combination with other astaxanthin color additive sources listed in this part 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements.* (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according

to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing *phaffia* yeast shall be declared in accordance with §§ 101.22(b), (c), and (k)(2) and 101.100(a)(2) of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: June 27, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Furazolidone Aerosol Powder

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 Fort Dodge Animal Health, a Division of American Cyanamid Co. The supplemental NADA provides for removal of that portion of the approval reflecting topical cattle use of furazolidone aerosol powder.

DATES: This regulation is effective July 6, 2000.

FOR FURTHER INFORMATION CONTACT:

Mohammad I. Sharar, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6642.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, a Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, is the sponsor of NADA 32-319 for Furox (furazolidone) aerosol powder for use in dogs, horses, ponies, and cattle. The sponsor filed a supplemental NADA requesting removal of topical ocular use of the product in cattle. The supplemental NADA is approved as of November 29, 1999, and the regulations are amended in 21 CFR

524.1005(b)(1), (c)(2)(iii), and (c)(3) to reflect the approval.

The regulations in § 524.1005(b)(1) (21 CFR 524.1005(b)(1)) indicate that Pfizer, Inc., is sponsor of NADA 32-319 for use of a 10 percent furazolidone aerosol powder in dogs, horses, and cattle. The NADA had been acquired by Fort Dodge Animal Health, a Division of American Cyanamid Co. At this time, the regulation is amended in § 524.1005(b) to reflect the sponsor change.

Approval of this supplemental NADA provides for removal of a cattle use. It does not affect the safety or effectiveness data in the application. Therefore, a freedom of information summary is not 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 congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.1005 is amended by revising paragraphs (b)(1) and (c)(3) and by removing and reserving paragraph (c)(2)(iii) to read as follows:

§ 524.1005 Furazolidone aerosol powder.

* * * * *

(b) * * *

(1) See No. 053501 in § 510.600(c) of this chapter for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii), and (c)(3) of this section.

* * * * *

(c) * * *

(2) * * *

(iii) [Reserved]

(3) Limitations. For topical application in horses, ponies, and dogs: Clean affected area thoroughly, apply drug once or twice daily, and repeat treatment as required. Use only as recommended by a veterinarian in treatment of puncture wounds, wounds requiring surgical debridement or suturing, those of a chronic nature involving proud flesh, generalized and

chronic infections of the skin, and those skin conditions associated with intense itching. If redness, irritation, or swelling persists or increases, discontinue use and consult a veterinarian. Not for use in horses intended for food.

Dated: June 15, 2000.

Andrew J. Beaulieu, Deputy Director, Center for Veterinary Medicine.

[FR Doc. 00-16977 Filed 7-5-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Fenbendazole

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 Hoechst Roussel Vet. The supplemental NADA provides for establishing tolerances for residues of fenbendazole in edible tissues of cattle. Also, a tolerance for parent fenbendazole in goat muscle is established.

DATES: This rule is effective July 6, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010, filed a supplement to NADA 128-620 that provides for use of Safe-Guard® (fenbendazole) 10% Suspension for Cattle and Panacur® (fenbendazole) 10% Suspension for Cattle. The supplement provides for establishing a tolerance for parent fenbendazole in cattle muscle. The supplement is approved as of May 9, 2000, and the regulations in § 556.275 (21 CFR 556.275) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA is reviewing information in the application and it is establishing a tolerance for parent fenbendazole in goat muscle. The

regulations are further amended in § 556.275 to reflect this action.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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 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 part 556 is amended as follows:

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

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

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

2. Section 556.275 is amended by adding paragraphs (b)(1)(ii) and (b)(3)(ii) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(1) * * *

(ii) Muscle. The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

* * * * *

(3) * * *

(ii) Muscle. The tolerance for parent fenbendazole (the marker residue) is 0.4 ppm.

Dated: June 19, 2000.

Claire M. Lathers, Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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