animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Combe, Inc. The supplemental NADA provides for the topical use of 2-mercaptobenzothiazole solution as an aid in the treatment of certain common skin inflammations in dogs.

DATES: This rule is effective August 22, 2000.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Combe, Inc., 1101 Westchester Ave., White Plains, NY 10604, filed a supplement to NADA 5–236 that provides for the use of Sulfodene® (2-mercaptobenzothiazole) skin medication for dogs as an aid in the treatment of hot spots (moist dermatitis) and as first aid for scrapes and abrasions. The supplemental NADA provides for revisions to labeling. The NADA is approved as of July 3, 2000, and the regulations in 21 CFR 524.1376 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of any safety or effectiveness data. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(d)(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 524

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 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.

§ 524.1376 [Amended]

2. Section 524.1376 *2-Mercaptobenzothiazole solution* is amended in paragraph (c)(2) by removing the phrase ''treating moist dermatitis and hot spots'' and by adding in its place the phrase ''the treatment of hot spots (moist dermatitis)''.

Dated: July 21, 2000.

Claire M. Lathers,

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

[FR Doc. 00–21414 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; 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 use of an approved fenbendazole Type A medicated article to make Type B and Type C medicated feeds used for the removal and control of gastrointestinal worms in growing turkeys. Also, tolerances for fenbendazole residues in turkey liver and muscle are being established.

DATES: This rule is effective August 22, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), 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 131–675 that provides for the use of Safe–Guard® (fenbendazole) 20% Type A medicated article to make Type B and Type C medicated feeds for cattle, swine, and zoo and wildlife animals. The supplemental NADA provides for the use of the approved fenbendazole Type A medicated article to make Type B and Type C medicated feeds used for the removal and control of gastrointestinal worms: Round worms, adult and larvae (*Ascaridia dissimilis*) and cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead) in growing turkeys. Also, tolerances for fenbendazole sulfone in turkey liver and muscle are established. The supplemental NADA is approved as of July 3, 2000, and the regulations are amended in §§ 556.275 and 558.258 (21 CFR 556.275 and 558.258) to reflect the approval.

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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on July 3, 2000, because the 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 the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency'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 (address above) 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

21 CFR Part 556

Animal drugs, Food.

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 parts 556 and 558 are 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 redesignating paragraph (b)(3) as paragraph (b)(4) and by adding new paragraph (b)(3) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(3) *Turkeys*—(i) *Liver (the target tissue*). The tolerance for fenbendazole sulfone (the marker residue) is 6 ppm.

(ii) *Muscle*. The tolerance for fenbendazole sulfone (the marker residue) is 2 ppm.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

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

4. Section 558.258 is amended by redesignating paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) as paragraphs (d)(2), (d)(3), (d)(4), and (d)(5) and by adding new paragraph (d)(1) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(d) * * *

(1) *Turkeys*—(i) *Amount*. Fenbendazole, 14.5 grams per ton (16 parts per million).

(A) *Indications for use*. For the removal and control of gastrointestinal worms: Round worms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).

(B) *Limitations*. Feed continuously as the sole ration for 6 days. For growing turkeys only.

(ii) [Reserved]

* * * * *

Dated: July 25, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–21413 Filed 8–21–00; 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; Bacitracin Methylene Disalicylate, Robenidine Hydrochloride, and Roxarsone

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 new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved bacitracin methylene disalicylate (BMD), robenidine hydrochloride, and roxarsone Type A medicated articles to make three-way combination Type C medicated broiler chicken feeds used for prevention of coccidiosis; as an aid in the prevention and control of necrotic enteritis; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

DATES: This rule is effective August 22, 2000.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–155 that provides for use of BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD), ROBENZ® (30 g/lb robenidine hydrochloride), and 3-NITRO® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make three-way combination Type C medicated feeds containing 30 g/ton robenidine hydrochloride, 22.7 to 45.4 g/ton roxarsone, and 50 or 100 to 200 g/ton BMD for use in broiler chickens.

The combination Type C medicated feeds containing 50 g/ton BMD are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. The combination Type C medicated feeds containing 100 to 200 g/ton BMD are used for prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. The NADA is approved as of July 3, 2000, and the regulations are amended in §§ 558.76 and 558.515 (21 CFR 558.76 and 558.515) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 558.76 is also amended editorially to consolidate the cross-references for approved combinations in paragraph (d)(3) and list them in alphabetical order. Section 558.515 is amended editorially to display the conditions of use in paragraph (d) in a table format.

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)(2) 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 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.

2. Section 558.76 is amended by revising paragraph (d)(3) to read as follows: