that registered FCMs are not small entities for the purposes of the RFA.[7] With respect to IBIs, the Commission stated that it is appropriate to evaluate within the context of a particular rule whether some or all introducing broker should be considered to be small entities and, if so, to analyze the economic impact on such entities at that time.[8] The amendments to Rule 1.17(c)(5)(xiii) expanding the amount of funds that may be excluded from the foreign brokers receivable capital charge do not impose additional requirements on an IBI. Therefore, the Chairman, on behalf of the Commission, certifies that these regulations will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act

The Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* (Supp. I 1995), imposes certain requirements on federal agencies (including the Commission) to review rules and rule amendments to evaluate the information collection burden that they impose on the public. The Commission believes that the amendments to Rule 1.17(c)(5)(xiii) will impose a minimal information collection burden on the public, namely those FCMs and IBIs who wish to take advantage of the exemption will be required to maintain a record of the margins required to be on deposit with a foreign broker over the preceding six month period. However, this burden is believed to be minimal when compared to the capital savings to be generated by the exclusion of increased amounts from the capital charge.

List of Subjects in 17 CFR Part 1

Brokers, Commodity futures.

In consideration of the foregoing and pursuant to the authority contained in the Commodity Exchange Act and, in particular, Sections 4(b), 4f, 4g, and 8a(5) thereof, 7 U.S.C. 6(b), 6d, 6g, and 12a(5), the Commission hereby amends Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

1. The authority citation for Part 1 continues to read as follows:

Authority. 7 U.S.C. 1a, 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k,6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, and 24.

2. Section 1.17 is amended by revising paragraph (c)(5)(xiii) to read as follows:

§1.17 Minimum financial requirements for futures commission merchants and introducing brokers.

* * * * *

(c) * * *

(5) * * *

(xiii) Five percent of all unsecured receivables includable under paragraph (c)(2)(ii)(D) of this section used by the applicant or registrant in computing ''net capital'' and which are not due from:

(A) A registered futures commission merchant;

(B) A broker or dealer that is registered as such with the Securities and Exchange Commission; or

(C) A foreign broker that has been granted comparability relief pursuant to §30.10 of this chapter, *Provided, however,* that the amount of the unsecured receivable not subject to the five percent capital charge is no greater than 150 percent of the current amount required to maintain futures and option positions in accounts with the foreign broker, or 100 percent of such greater amount required to maintain futures and option positions in the accounts at any time during the previous six-month period, and *Provided, that,* in the case of customer funds, such account is treated in accordance with the special requirements of the applicable Commission order issued under §30.10 of this chapter.

* * * * *

Issued in Washington, DC, on November 1, 2000, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 00–28492 Filed 11–6–00; 8:45 am]

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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; Enrofloxacin, Silver Sulfadiazine Emulsion

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 Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use of an enrofloxacin/silver sulfadiazine otic emulsion to treat otitis externa in dogs.

DATES: This rule is effective November 7, 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: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141–176 that provides for veterinary prescription use of BAYTRIL® (0.5 % enrofloxacin/1.0% silver sulfadiazine) Otic Emulsion for the treatment of otitis externa in dogs. The NADA is approved as of September 29, 2000, and the regulations are amended in 21 CFR part 524 by adding new section 524.802 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 29, 2000, because the application contains substantial evidence of effectiveness of the drug involved, or any studies of animal safety, required for approval of the application and conducted or sponsored by the applicant.

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.

[7] 47 FR 18619–1820.

[8] 48 FR 35248, 35275–78 (August 3, 1983).

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.

2. Section 524.802 is added to read as follows:

§ 524.802 Enrofloxacin, silver sulfadiazine emulsion.

(a) *Specifications*. Each milliliter contains 5 milligrams (mg) enrofloxacin and 10 mg silver sulfadiazine.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—Dogs*—(1) *Amount*. 5 to 10 drops for dogs weighing 35 pounds (lb) or less and 10 to 15 drops for dogs weighing more than 35 lb; applied twice daily for up to 14 days.

(2) *Indications for use*. For the treatment of otitis externa in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

Dated: October 26, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–28520 Filed 11–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Decoquinate and Chlortetracycline

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 decoquinate and chlortetracycline (CTC) Type A medicated articles to make two-way combination Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle used for prevention of coccidiosis, treatment of bacterial enteritis, and treatment of bacterial pneumonia.

DATES: This rule is effective November 7, 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: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–147 that provides for use of Deccox® (27.2 grams per pound g/lb) and ChlorMax™ (50, 65, or 70 g/lb CTC) Type A medicated articles to make combination drug Type B and Type C medicated feeds for calves, beef and nonlactating dairy cattle. The combination Type C feeds are for prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, for treatment of bacterial enteritis caused by *Escherichia coli*, and for treatment of bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to CTC. The NADA is approved as of September 29, 2000, and the regulations are amended in the table in 21 CFR 558.195(d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 the 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 558.195 is amended in the table in paragraph (d) by adding an entry following the indication for ''Cattle'' at the 13.6 to 27.2 grams per ton decoquinate dose level and before the entry for ''Cattle'' at the 13.6 to 535.7 grams per ton dose level, to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *