

(E) Any account manager that believes he or she is or may be adversely affected or aggrieved by action taken by the Commission under paragraph (a-1)(5)(iv)(D) of this section shall have the opportunity for a prompt hearing in accordance with the provisions of § 21.03(g) of this chapter.

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Issued in Washington, DC, on June 5, 2003 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 03-14776 Filed 6-10-03; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 201

[Docket No. RM02-7-000; Order No. 631]

Accounting, Financial Reporting, and Rate Filing Requirements for Asset Retirement Obligations; Notice of Correction

June 3, 2003.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; correction.

SUMMARY: The Federal Energy Regulatory Commission published in the **Federal Register** of April 21, 2003, a final rule amending its accounting and reporting requirements for asset retirement obligations. Inadvertently, account 364.9, asset retirement costs for base load liquefied natural gas terminaling and processing plant, and related instruction was not included in the Gas Plant Accounts in the natural gas companies' Uniform System of Accounts. This correction includes the account in the Uniform System of Accounts.

DATES: Effective on June 11, 2003.

FOR FURTHER INFORMATION CONTACT: Mark Klose (Project Manager), Office of the Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502-8283.

SUPPLEMENTARY INFORMATION: The Federal Energy Regulatory Commission published in the **Federal Register** of April 21, 2003, (68 FR 19610) a final rule amending its accounting and financial reporting requirements for asset retirement obligations. Inadvertently, Gas Plant Account 364.9 (Asset retirement costs for base load liquefied natural gas terminaling and

processing plant) and the instruction related to this account were not incorporated into the Uniform System of Accounts for natural gas companies in part 201 of the Commission's regulations. To address this omission, the Commission will publish in the **Federal Register** the following correction to the final rule document that was published in the **Federal Register** at 68 FR 19610, on April 21, 2003.

■ In rule FR Doc. 03-9260 published on April 21, 2003 (68 FR 19610) make the following correction.

■ On page 19624, in the second column, account 364.9 is added to part 201 in Gas Plant Accounts following account 363.6 to read as follows:

Gas Plant Accounts

* * * * *

364.9 Asset retirement costs for base load liquefied natural gas terminaling and processing plant.

This account shall include asset retirement costs on plant included in the base load liquefied natural gas terminaling and processing plant function.

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Magalie R. Salas,

Secretary.

[FR Doc. 03-14561 Filed 6-10-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tepoxalin

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 Schering-Plough Animal Health Corp. The NADA provides for the veterinary prescription use of tepoxalin tablets for the control of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective June 11, 2003.

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, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141-193 that provides for veterinary prescription use of ZUBRIN (tepoxalin) Tablets for the control of pain and inflammation associated with osteoarthritis in dogs. The NADA is approved as of March 31, 2003, and the regulations in part 520 (21 CFR part 520) are amended by adding new § 520.2340 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 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 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)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 31, 2003.

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 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. Section 520.2340 is added to read as follows:

§ 520.2340 Tepoxalin.

(a) *Specifications.* Each tablet contains 30, 50, 100, or 200 milligrams (mg) tepoxalin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* 10 mg per kilogram (kg) daily; or 20 mg/kg on the initial day of treatment, followed by 10 mg/kg daily.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 27, 2003.

Steven F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–14678 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Injectable or Implantable Dosage Form New Animal Drugs; Carprofen

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 Pfizer, Inc. The supplemental NADA provides for a once daily, 2-milligram-per-pound dosage of carprofen solution, by subcutaneous injection, for the relief of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective June 11, 2003.

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, e-mail mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed a supplement to NADA 141–199 for RIMADYL (carprofen) Injectable used for the relief of pain and inflammation associated with osteoarthritis in dogs. The supplemental NADA provides for veterinary prescription use of a once daily, 2-milligram-per-pound dosage of carprofen solution by subcutaneous injection. The supplemental application is approved as of March 25, 2003, and the regulations are amended in 21 CFR 522.312 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 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 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 Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning March 25, 2003.

The agency has determined under § 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. Section 522.312 is amended by revising (d)(1) to read as follows:

§ 522.312 Carprofen.

* * * * *

(d) * * *

(1) *Amount.* 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection.

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Dated: May 29, 2003.

Steven D. Vaughn,

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

[FR Doc. 03–14544 Filed 6–10–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. 91N–0278]

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to correct certain errors that were incorporated into the regulations. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective June 11, 2003.

FOR FURTHER INFORMATION CONTACT:

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA has discovered certain errors that were inadvertently included in the agency’s codified regulations for part 601 (21 CFR part 601). In the **Federal Register** of December 11, 1992 (57 FR 58942), we published a final rule that, among other things, established subpart E of part 601, which encompasses §§ 601.40 through 601.46. Currently, § 601.43(a) refers to § 601.40, instead of the correct § 601.41; § 601.43(b) refers to § 601.40, instead of the correct § 601.42. Accordingly, we are amending § 601.43(a) by replacing the incorrect reference to § 601.40 with a reference to § 601.41, and we are amending § 601.43(b) by replacing the incorrect reference to § 601.40 with a reference to § 601.42. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive.

List of Subjects in 21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 601 is amended as follows: