(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.

* * * * *

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: