Firm name and address	Drug labeler code
* * * * * * *	
Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	051311
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051311	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137
* * * * * * *	

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1193 [Amended]

4. Section 524.1193 *Ivermectin pour-on* is amended in paragraph (b) by adding ''051311,'' after ''051259,'' and in paragraph (e)(2) by removing ''Damalina'' and by adding in its place ''Damalinia''.

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–30037 Filed 12–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen

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 Pfizer, Inc. The supplemental NADA provides for a once daily, 2-milligram per pound (mg/lb) dosage of carprofen, by oral caplet, for the relief of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective December 5, 2001.

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: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed a supplement to approved NADA 141–053 that provides for veterinary prescription use of RIMADYL (carprofen) Caplets for the relief of pain and inflammation associated with osteoarthritis in dogs. The supplemental NADA provides for a once daily, 2-mg/lb dosage for the oral caplet dosage form. The supplemental application is approved as of September 27, 2001, and the regulations are amended in 21 CFR 520.309 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for non-food-producing animals qualifies for 3 years of marketing exclusivity beginning September 27, 2001, 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 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 520.309 is amended in paragraph (a) by adding ''(mg)'' after ''milligrams''; and by revising paragraph (d) to read as follows:

§ 520.309 Carprofen.

* * * * *

(d) *Conditions of use in dogs*—(1) *Amount*—(i) *Caplet.* 2 mg per pound (/lb) of body weight once daily or 1 mg/lb twice daily.

(ii) *Chewable tablet.* 1 mg/lb twice daily.

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

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

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–30039 Filed 12–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 an abbreviated new animal drug application (ANADA) filed by First Priority, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective December 5, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–321 for PRIMECTIN™ (ivermectin) Equine Oral Liquid. The application provides for oral use of a 1.0 percent ivermectin solution in horses for the treatment and control of various species of gastrointestinal nematodes, lungworms, stomach bots, and cutaneous larvae and microfilariae. First Priority's PRIMECTIN™ Equine Oral Liquid is approved as a generic copy of Merial Ltd.'s EQVALAN® (ivermectin) Oral Liquid for Horses, approved under NADA 140–439. ANADA 200–321 is approved as of September 7, 2001, and 21 CFR 520.1195 is amended 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)(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 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 520.1195 is amended in paragraph (b) by adding ''058829,'' after ''051259''; by revising the heading of paragraph (c) and paragraph (c)(1); in paragraph (c)(2) by removing ''It is used in horses''; and in paragraph (c)(3) by removing the first sentence to read as follows:

§ 520.1195 Ivermectin liquid.

* * * * *

(c) *Conditions of use in horses*—(1) *Amount.* 200 micrograms per kilogram of body weight as a single dose by stomach tube or as an oral drench.

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–30076 Filed 12–4–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[AZ060–OPP; FRL–7112–8]

Clean Air Act Full Approval of the Operating Permits Program for the Pinal County Air Quality Control District, AZ

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is taking final action to fully approve the Pinal County Air Quality Control District (Pinal or District) operating permits program. The Pinal program was submitted in response to the directive in the 1990 Clean Air Act (CAA) Amendments that permitting authorities develop, and submit to EPA, programs for issuing operating permits to all major stationary sources and to certain other sources within the permitting authorities' jurisdiction. On October 30, 1996, EPA granted interim approval to Pinal's operating permits program. The District revised its program to satisfy the conditions of the interim approval, and EPA proposed full approval in the **Federal Register** on September 20, 2001, contingent upon Pinal submitting the rules to EPA as a revision to its part 70 program. Pinal County did so, and EPA did not receive any comments on the proposed action. This action promulgates final full approval of the Pinal operating permits program.

EFFECTIVE DATE: This rule is effective on November 30, 2001.

ADDRESSES: Copies of Pinal's submittal and other supporting information used in developing this final full approval are available for inspection during normal business hours at the following location: U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105. You may also see copies of the submitted title V program at the following location: Pinal County Air Quality Control District, Building F, 31 North Pinal Street, Florence, Arizona 85232.

FOR FURTHER INFORMATION CONTACT: Emmanuelle Rapicavoli, EPA Region 9, at (415) 972–3969 or rapicavoli.emmanuelle@epa.gov.

SUPPLEMENTARY INFORMATION: This section contains additional information about our final rulemaking, organized as follows:

I. Background on the Pinal County Air Quality Control District Operating Permits Program

The Clean Air Act (CAA) Amendments of 1990 required all state and local permitting authorities to develop operating permits programs that meet certain federal criteria. Pinal's operating permits program was submitted in response to this directive. Because the District program