SUPPLEMENTARY INFORMATION:

History

On October 16, 1996, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR part 71) by revoking the Class E airspace area at Alameda, CA (61FR 53880). This action will revoke controlled airspace since the purpose and requirements for the surface area no longer exist at Alameda NAS (Nimitz Field), CA. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposals to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6002 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be removed subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) revokes the Class E airspace area at Alameda, CA. The base closure of Alameda Naval Air Station (NAS) has made this action necessary. The intended effect of this action is to revoke controlled airspace since the purpose and requirements for the surface area no longer exist at Alameda NAS (Nimitz Field), CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6002 Class E airspace.

* * * * *

AWP CA E2 Alameda NAS, CA [Removed]

* * * * *

Issued in Los Angeles, California, on November 29, 1996.

Sabra W. Kaulia,

Assistant Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 96–32017 Filed 12–17–96; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Mallinckrodt Veterinary, Inc., to Veterinary Specialties, Inc.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION:

Mallinckrodt Veterinary, Inc., Mundelein, IL 60060, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 65–107 for entromycin powder to Veterinary Specialties, Inc., 387 North Valley Ct., Barrington, IL 60010. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Veterinary Specialties, Inc. The agency is also amending 21 CFR 520.154b to reflect the transfer of ownership.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Veterinary Specialties, Inc.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''062925'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Veterinary Specialties, Inc., 387 North Valley Ct., Barrington, IL 60010	062925
* * * * *	

(2) * * *

Drug labeler code	Firm Name and address
* * * * *	
062925	Veterinary Specialties, Inc., 387 North Valley Ct., Barrington, IL 60010
* * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.154b [Amended]

4. Section 520.154b *Soluble bacitracin methylene disalicylate and streptomycin sulfate oral powder* is amended in paragraph (b) by removing ''011716'' and adding in its place ''062925''.

Dated: December 5, 1996.

Robert C. Livingston,

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

[FR Doc. 96–32067 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Carprofen Caplets

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 Pfizer, Inc. The NADA provides for oral use of nonsteroidal anti-inflammatory carprofen caplets in dogs for relief of pain and inflammation. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–053, which provides for oral use of carprofen caplets in dogs for the relief of pain and inflammation. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis. The drug product is restricted to veterinary prescription use only. The NADA is approved as of October 25, 1996, and the regulations are amended by adding new 21 CFR 520.309 to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning October 25, 1996, because no active ingredient (including any ester or salt thereof) of the drug has been approved previously in any other NADA.

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.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.309 is added to read as follows:

§ 520.309 Carprofen caplets.

(a) *Specification*. Each caplet contains 25, 75, or 100 milligrams of carprofen.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 1 milligram per pound of body weight twice daily. Caplets are scored and dosage should be calculated in half-caplet increments.

(2) *Indications for use.* For the relief of pain and inflammation in dogs. Carprofen has been shown to be clinically effective for the relief of signs associated with osteoarthritis in dogs.

(3) *Limitations.* The safe use of carprofen in pregnant dogs, dogs used for breeding purposes, or in lactating bitches has not been established. As a class, cyclo-oxygenase inhibitory nonsteroidal anti-inflammatory drugs (NSAID's) may be associated with gastrointestinal and renal toxicity. Patients at greatest risk for renal toxicity are those on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction. Because many NSAID's possess the potential to induce gastrointestinal ulceration, avoid or closely monitor concomitant use of carprofen with other anti-inflammatory drugs, such as corticosteroids and NSAID's. Carprofen treatment was not associated with renal toxicity or gastrointestinal ulceration in safety studies of up to 10 times the dose in dogs. Do not use in dogs with bleeding disorders (e.g., Von Willebrand's disease). Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 6, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–32068 Filed 12–17–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

New Animal Drugs and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Pfizer, Inc., to Intervet, Inc.

EFFECTIVE DATE: December 18, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 140–857 (luprostiol sterile solution) to Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966. Accordingly, FDA is amending the regulations in 21 CFR 522.1290 to reflect the change of sponsor.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under