Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6556.

SUPPLEMENTARY INFORMATION:

History

On November 20, 1996, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by revising the Class E airspace area at Victorville, CA (61 FR 59042). This action will provide adequate controlled airspace to accommodate IFR operations at Southern California International Airport, Victorville, CA.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in paragraph 6005 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 published subsequently in this Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at Victorville, CA. The closure of George Air Force Base has made this action necessary. The effect of this action will provide adequate controlled airspace for IFR operations at Southern California International Airport, Victorville, 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 6005 Class E Airspace

* * * * *

AWP CA E5 Victorville, CA [Revised]

Victorville, Southern California International Airport, CA
(Lat. 34°35′67″ N, long. 117°22′93″ W)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the Victorville, Southern California International Airport, CA.

* * * * *

Issued in Los Angeles, California on February 5, 1997.

Leonard A. Mobley,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 97–4577 Filed 2–24–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Monensin Blocks; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of October 15, 1996 (61 FR 53614). The document amended the animal drug regulations to reflect approval of supplemental new animal drug applications filed by Cooperative Research Farms and PM Ag Products, Inc. The document was published with an incorrect approval date. This document corrects that error.

EFFECTIVE DATE: October 15, 1996.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

In FR Doc. 96–26374, appearing on page 53614, in the Federal Register of Tuesday, October 15, 1996, the following correction is made:

1. On page 53615, in the first column under the ''SUPPLEMENTARY INFORMATION'' caption, in line 14, ''September 10, 1996'' is corrected to read ''October 15, 1996''.

Dated: February 10, 1997.

Robert C. Livingston,

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

[FR Doc. 97–4518 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfadimethoxine Oral Solution

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 Fermenta Animal Health. The ANADA provides for use of sulfadimethoxine oral solution to prepare medicated drinking water for animals to treat bacterial infections sensitive to sulfadimethoxine.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, filed ANADA 200–165, which provides for use of sulfadimethoxine 12.5 percent oral solution to prepare medicated drinking water for broiler and replacement chickens, meat-producing turkeys, and dairy calves, dairy heifers, and beef cattle for the treatment of bacterial diseases susceptible to sulfadimethoxine.

Fermenta Animal Health's ANADA 200–165 for sulfadimethoxine oral solution 12.5 percent is approved as a generic copy of Hoffmann-LaRoche's Albon/Agribon (sulfadimethoxine) 12.5 percent solution in NADA 31–205. The ANADA is approved as of December 4,

1996, and the regulations are amended by revising 21 CFR 520.2220a(b) 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually of cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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).

§ 520.2220a [Amended]

2. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (b) by removing ''000069 and 057561'' and adding in its place ''000069, 054273, and 057561''.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–4515 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Suspension and Tablets

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 two supplemental new animal drug applications (NADA's) filed by Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplements provide that veterinary prescriptions are no longer required for use of lufenuron tablets for dogs and oral suspension for cats.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish P1., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, filed supplemental NADA 141–026 that provides for oral administration of Program® (lufenuron) suspension for cats and kittens for control of flea populations and supplemental NADA 141–035 that provides for oral administration of Program® (lufenuron) tablets for dogs and puppies for prevention and control of flea populations. The supplemental NADA's provide that veterinary prescriptions are no longer required. The supplemental NADA's are approved as of December 31, 1996, and the regulations are amended by revising 21 CFR 520.1288(c)(3) and 520.1289(c)(3) to remove the limitation for veterinary prescription use.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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).

§ 520.1288 [Amended]

2. Section 520.1288 *Lufenuron tablets* is amended in paragraph (c)(3) by removing the last sentence.

§ 520.1289 [Amended]

3. Section 520.1289 *Lufenuron suspension* is amended in paragraph (c)(3) by removing the last sentence.

Dated: February 3, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–4513 Filed 2–24–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Progesterone and Estradiol Benzoate

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 Ivy Laboratories, Inc. The supplemental NADA provides for use of a progesterone-estradiol benzoate ear implant in suckling beef heifer calves for increased rate of weight gain.

EFFECTIVE DATE: February 25, 1997.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to NADA 110–315, which provides for use of a progesterone-estradiol benzoate ear implant in suckling beef heifer calves for increased rate of weight gain. Studies have shown no detrimental effects on reproduction after use of the implants in heifer calves. The supplement is approved as of January 22, 1997, and the regulations are amended in 21 CFR 522.1940(d)(1)(iii) to reflect the approval by limiting the use to indicate