listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace located at Gallup Municipal Airport, Gallup, NM, to provide controlled airspace extending upward from 700 feet AGL for aircraft executing the GPS SIAP to RWY 24.

The FAA has determined that this regulation only involves an established body of technical regulations that need frequent and routine amendments to keep them operationally current. It, therefore—(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 11035; 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 Subject 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. 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 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 areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASW NM E5 Gallup, NM [Revised]

Gallup Municipal Airport, NM
(Lat 35°30′40″N., long 108°47′22″W.)
Gallup VORTAC
(Lat. 35°28′34″N., long 108°52′21″W.)
Gallup ILS Localizer
(Lat 35°30′53″N., long 108°46′28″W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Gallup Municipal Airport and within 1.9 miles each side of the Gallup ILS Localizer southwest course extending from the 6.7-mile radius to 12.6 miles southwest of the airport and within 2 miles each side of the 074° bearing from the airport extending from the 6.7-mile radius to 9.1 miles east of the airport and within 1.3 miles each side of the 242° radial of the Gallup VORTAC extending from the 6.7-mile radius to 11.5 miles southwest of the airport and that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at lat 35°47′30″N, long 108°34′02″W; to lat 35°26′50″N, long 108°34′02″W; to lat 35°13′15″N, long 109°06′02″W' to lat 35°20′25″N, long 109°10′42″W; to lat 35°52′00″N, long 108°47′02″W; to point of beginning excluding that airspace within the New Mexico, NM, Class E airspace area.

* * * * *

Issued in Fort Worth, TX, on March 7, 1997.

Albert L. Viselli,

Acting Manager, Air Traffic Division, Southwest Region.

[FR Doc. 97–6529 Filed 3–13–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 200, 250, and 310

[Docket No. 96N–0183]

RIN 0910–AA53

Consolidation of Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is consolidating a list of drugs, previously determined by rulemaking to be new drugs, into one section. This document also removes the sections now providing for these drugs, except for certain information in the regulations that FDA considers to be necessary. This action, which will make the regulations more concise and efficient, is being taken in response to the President's regulatory reinvention initiative (REGO).

EFFECTIVE DATE: April 14, 1997.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Food and Drug Administration, Center for Drug Evaluation and Research (HFD–7), 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton issued a memorandum titled ''Regulatory Reinvention Initiative,'' which directed all Federal agencies to conduct a page-by-page review of their existing regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' As a result of that review and as part of its response to the President's directive, FDA published a document in the Federal Register of June 11, 1996 (61 FR 29502), proposing to amend those parts of its drug regulations codified in parts 200, 250, and 310 (21 CFR parts 200, 250, and 310), regarding certain drugs determined by rulemaking to be new drugs.

FDA proposed the following: (1) To revise § 310.502 to consolidate into one section a list of drugs (now codified in parts 200, 250, and 310) that have been determined by rulemaking procedures to be new drugs requiring approved new drug applications, and (2) to remove those sections in parts 200, 250, and 310 now providing for those drugs, except for certain information in § 310.509 that FDA considers to be necessary. The agency received no comments in response to the proposal to amend or remove these regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 200, 250, and 310 are amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

Subpart B [Removed]

2. Subpart B, consisting of §§ 200.30 and 200.31 is removed and reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

3. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.10 [Removed]

4. Section 250.10 *Oral prenatal drugs containing fluorides intended for human use* is removed.

§ 250.103 [Removed]

5. Section 250.103 *Thorium dioxide for drug use* is removed.

§ 250.106 [Removed]

6. Section 250.106 *Cobalt preparations intended for use by man* is removed.

PART 310—NEW DRUGS

7. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

8. Section 310.502 is revised to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. Except as provided in paragraph (b) of this section, an approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

(1) Aerosol drug products for human use containing 1,1,1-trichloroethane.

(2) Aerosol drug products containing zirconium.

(3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.

(4) Camphorated oil drug products.

(5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4′,5-tribromosalicylanilide), dibromsalan (DBS, 4′, 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3′, 4,5′-tetrachlorosalicylanilide (TC–SA)) as an ingredient in drug products.

(6) Chloroform used as an ingredient (active or inactive) in drug products.

(7) Cobalt preparations intended for use by man.

(8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.

(9) Oral prenatal drugs containing fluorides intended for human use.

(10) Parenteral drug products in plastic containers.

(11) Sterilization of drugs by irradiation.

(12) Sweet spirits of nitre drug products.

(13) Thorium dioxide for drug use.

(14) Timed release dosage forms.

(15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) Any drug listed in paragraph (a) of this section, when composed wholly or partly of any antibiotic drug, must be certified under section 507 of the act or exempted from certification under section 507 of the act for marketing.

§ 310.504 [Removed]

9. Section 310.504 *Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use* is removed.

§ 310.506 [Removed]

10. Section 310.506 *Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products* is removed.

§ 310.507 [Removed]

11. Section 310.507 *Aerosol drug products for human use containing 1,1,1-trichloroethane* is removed.

§ 310.508 [Removed]

12. Section 310.508 *Use of certain halogenated salicylanilides as an inactive ingredient in drug products* is removed.

13. Section 310.509 is revised to read as follows:

§ 310.509 Parenteral drug products in plastic containers.

(a) Any parenteral drug product packaged in a plastic immediate container is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the act, and requires an approved new drug application as a condition for marketing. An ''Investigational New Drug Application'' set forth in part 312 of this chapter is required for clinical investigations designed to obtain evidence of safety and effectiveness.

(b) As used in this section, the term ''large volume parenteral drug product'' means a terminally sterilized aqueous drug product packaged in a single-dose container with a capacity of 100 milliliters or more and intended to be administered or used intravenously in a human.

(c) Until the results of compatibility studies are evaluated, a large volume parenteral drug product for intravenous use in humans that is packaged in a plastic immediate container on or after April 16, 1979, is misbranded unless its labeling contains a warning that includes the following information:

(1) A statement that additives may be incompatible.

(2) A statement that, if additive drugs are introduced into the parenteral system, aseptic techniques should be used and the solution should be thoroughly mixed.

(3) A statement that a solution containing an additive drug should not be stored.

(d) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

§ 310.510 [Removed]

14. Section 310.510 *Use of aerosol drug products containing zirconium* is removed.

§ 310.513 [Removed]

15. Section 310.513 *Chloroform, use as an ingredient (active or inactive) in drug products* is removed.

§ 310.525 [Removed]

16. Section 310.525 *Sweet spirits of nitre drug products* is removed.

§ 310.526 [Removed]

17. Section 310.526 *Camphorated oil drug products* is removed.

Dated: March 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–6411 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lufenuron Tablet

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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for oral administration of lufenuron tablets at a minimum dose of 30 milligrams per kilogram (mg/kg) for the control of flea populations on cats.

EFFECTIVE DATE: March 14, 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 141–035, which provides for oral administration of Program® (lufenuron) tablets to cats 6 weeks of age or older. The drug is approved in 90- or 204.9-mg tablets, given once a month, directly or broken and mixed into wet food, for the control of flea populations. Lufenuron has no deleterious effect on adult fleas but it prevents most flea eggs from hatching or maturing into adults. The supplemental NADA is approved as of January 23, 1997, and the regulations are amended in 21 CFR 520.1288 by revising the heading for paragraph (c) and by adding new paragraph (d) 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 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning January 23, 1997, because the application contains substantial evidence of effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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.

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. Section 520.1288 is amended by revising the heading for paragraph (c) and by adding new paragraph (d) to read as follows:

§ 520.1288 Lufenuron tablets.

* * * * *

(c) *Conditions of use in dogs*—

* * * * *

(d) *Conditions of use in cats*—(1) *Amount.* 90-milligram tablet for cats up to 6 pounds of body weight, 204.9-milligram tablet for cats 7 to 15 pounds, a combination of tablets for cats over 15 pounds (a minimum of 13.6 milligrams per pound (30 milligrams per kilogram)).

(2) *Indications for use.* For control of flea populations.

(3) *Limitations.* For oral use in cats 6 weeks of age or older, once a month, directly or broken and mixed into wet food. Administer in conjunction with a full meal to ensure adequate absorption. Treat all cats in the household to ensure maximum benefits. Because the drug has no affect on adult fleas, the concurrent use of insecticides that kill adults may be necessary depending on the severity of the infestation.

Dated: February 11, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–6412 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline and Tiamulin

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 Fermenta Animal Health Co. The NADA provides for the use of separately approved Type A medicated articles containing chlortetracycline and tiamulin in making Type C combination medicated feed. The feed is used in swine for treatment of bacterial enteritis and bacterial pneumonia and for control of swine dysentery. The regulations are also amended to increase the tolerance for tiamulin residue in swine liver.

EFFECTIVE DATE: March 14, 1997

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153–2314, filed NADA 141–011,