

of the airport will change from Visual Flight Rules (VFR) operations concurrent with the publication of the SIAP.

EFFECTIVE DATE: 0901 UTC, November 4, 1999.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Manager, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5627.

SUPPLEMENTARY INFORMATION:

History

On May 28, 1999, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing Class E airspace at Avon Park, FL, (64 FR 28944). This action provides adequate Class E airspace for IFR operations at Avon park Municipal Airport. Designations for Class E airspace extending upward from 700 feet or more above the surface of the earth are published in FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR part 71.1. The Class E designation listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal was received.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Avon Park, FL. A GPS RWY 9 SIAP has been developed for Avon Park Municipal Airport. Controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAP and for IFR operations at Avon Park Municipal Airport. The operating status of the airport will change from VFR to include IFR operations concurrent with the publication of the SIAP.

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. 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 11034; 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—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS, ROUTES; AND REPORTING POINTS

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, EO 10854, 24 FR 9565, 3 CFR 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward from 700 feet or More Above the Surface of the Earth

* * * * *

ASO FL E5 Avon Park, FL [New]

Avon Park Municipal Airport
(Lat. 27°35'28"N, long. 81°31'40"W)

That airspace extending upward from 700 feet or more above the surface of the earth within a 6.6-mile radius of Avon Park Municipal Airport, excluding that airspace within the Sebring, FL Class E airspace area.

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Issued in College Park, Georgia, on June 29, 1999.

Nancy B. Shelton,

*Acting Manager, Air Traffic Division,
Southern Region.*

[FR Doc. 99-17760 Filed 7-12-99; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

21 CFR Parts 520 and 558

Animal Drugs, Feeds, and Related Products; Chlortetracycline Powder, Etc.; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to correct errors concerning the sponsor of oral chlortetracycline powder, oral tetracycline powder, and interim use of certain medicated feeds. The amendments are required because the regulations did not reflect a change of sponsor from Fermenta Animal Health to Boehringer Ingelheim Vetmedica.

EFFECTIVE DATE: July 13, 1999.

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: In the **Federal Register** of June 30, 1997 (62 FR 35075 through 35077), FDA published a document reflecting the change of sponsor of several new animal drug applications from Fermenta Animal Health Co. to Boehringer Ingelheim Vetmedica, Inc. (at that time known as Boehringer Ingelheim Animal Health, Inc.). In 21 CFR 520.445b(d)(4)(iii)(C) and 520.2345d(a)(1) the regulations failed to reflect the change from "054273" to "000010". Also, in 21 CFR 558.15(g)(1) and (g)(2), the regulation failed to reflect the change from "Fermenta Animal Health" to "Boehringer Ingelheim Vetmedica." At this time, the regulations in 21 CFR parts 520 and 558 are amended to reflect the change of sponsor.

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

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

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 520 and 558 are 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.

§ 520.445b [Amended]

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(4)(iii)(C) by removing "012286, 053389, and 054273" and adding in its place "000010, 012286, and 053389".

§ 520.2345d [Amended]

3. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing "054273," and adding "000010," before "046573".

PART 558— NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

4. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.15 [Amended]

5. Section 558.15 *Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals* is amended in paragraphs (g)(1) and (g)(2) by removing "Fermenta Animal Health Co." and adding in its place "Boehringer Ingelheim Vetmedica, Inc."

Dated: June 28, 1999.

Claire M. Lathers,

*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
[FR Doc. 99-17761 Filed 7-12-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration [DEA-183F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Ketamine into Schedule III

AGENCY: Drug Enforcement
Administration, Department of Justice.
ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance ketamine,

including its salts, isomers, and salts of isomers, into schedule III of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). As a result of this rule, the regulatory controls and criminal sanctions of schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of ketamine and products containing ketamine.

EFFECTIVE DATE: August 12, 1999.

FOR FURTHER INFORMATION CONTACT:

Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537; Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background

Ketamine hydrochloride is marketed in the United States as a general anesthetic for use in human medicine under the trade name Ketalar®. It is also marketed as a veterinary product under various names including Ketajet®, Ketaset®, and Vetalar®. Since 1992, more than 775 reports of ketamine diversion or abuse have been received by the DEA. More than 568 law enforcement reports described encounters of individuals who sold the drug, who had it in their possession and/or were under its influence. Veterinary clinic burglaries which were directed at ketamine were described also. The balance of the reports were of ketamine abuse related hospital emergency department visits.

The wide geographic distribution and prevalence of diversion and/or abuse of ketamine, the spreading notoriety of ketamine as a party drug, Special 'K' or 'K', and the involvement of teenagers and young adults caused the DEA to submit to the Department of Health and Human Services (DHHS) information related to each of the eight factors which are determinative of control under the CSA. The DHHS responded by letter, recommending that ketamine be added to schedule III.

The pharmacological and behavioral effects of ketamine are similar, but somewhat less intense and shorter in duration, to those of the schedule II substance, phencyclidine (PCP). Low dose intoxication with ketamine results in impaired attention, learning, and memory functions. Higher doses may result in ataxia, dizziness, elevated blood pressure, mental confusion, hyperexcitability, catalepsy (the inability to move), amnesia, convulsions, a delusional dream-like state, hallucinations, and psychosis. Long-term use of ketamine is associated with hallucinatory flashbacks, an

inability to concentrate, psychological dependence, and tolerance. Reports of ketamine abuse leading to physical or psychological dependence consistent with schedule III criteria have been published.

Diversion of ketamine pharmaceutical products from practitioners has been the most frequently documented source of the drug, with the primary sources being veterinary clinics. The liquid pharmaceutical product is injected or, more commonly, evaporated and the resultant power inhaled (snorted). Clandestine manufacture of ketamine has not been encountered. In contrast to that of PCP, the synthesis of ketamine is difficult.

Notice of Proposed Rule Making

Relying on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health in accordance with section 201(b) of the CSA [21 U.S.C. 811(b)], and the independent review of the DEA, the Deputy Administrator of the DEA, pursuant to Sections 201(a) and 201(b) of the CSA [21 U.S.C. 811(a) and 811(b)] proposed the placement of ketamine, including its salts, isomers, and salts of isomers, into schedule III of the CSA in an April 9, 1999, **Federal Register** notice (64 FR 17299). The notice provided an opportunity for all interested persons to submit their comments or objections in writing on the proposed scheduling of ketamine on or before June 8, 1999.

Comments

The DEA received five comments regarding the proposal. Comments in support of the proposal were received from the American Animal Hospital Association (AAHA), the American Veterinary Medical Association (AVMA), the American Association of Equine Practitioners (AAEP) and a practicing veterinarian. The AAHA, which represents 16,000 veterinary care providers, commented that the movement of ketamine into Schedule III was in the best interest of the veterinary industry and the general public. The AVMA, on behalf of 62,000 members, stated that the security and record keeping required of Schedule III controlled substances will prevent diversion and unauthorized use of ketamine while providing a reasonable mechanism for the continued, responsible use of ketamine for legitimate purposes by members of the veterinary profession. The AAEP which reaches 3.2 million horse owners through its more than 6,200 members world wide strongly supports the placement of ketamine into Schedule III.