

Issued in College Park, Georgia on December 10, 2010.

Barry A. Knight,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2010-0692; Airspace Docket No. 10-AEA-16]

Establishment of Class E Airspace; Crewe, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E Airspace at Crewe, VA, to accommodate the additional airspace needed for the Standard Instrument Approach Procedures (SIAPs) developed for Crewe Municipal Airport. This action enhances the safety and airspace management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective 0901 UTC, March 10, 2011. The Director of the **Federal Register** approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5610.

SUPPLEMENTARY INFORMATION:

History

On September 20, 2010, the FAA published in the **Federal Register** a notice of proposed rulemaking to establish Class E airspace at Crewe, VA (75 FR 57215) Docket No. FAA-2010-0692. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace

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

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 establishes the Class E airspace extending upward from 700 feet above the surface at Crewe, VA, to provide controlled airspace required to support the SIAPs developed for Crewe Municipal Airport. This action is necessary for the safety and management of IFR operations at the airports.

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, is non-controversial and unlikely to result in adverse or negative comments. 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, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it establishes Class E airspace at Crewe, VA.

Lists 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, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 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.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, effective September 15, 2010, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA VA E5 Crewe, VA [NEW]

Crewe Municipal Airport, VA
(Lat. 37°10'52" N., long. 78°05'54" W.)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Crewe Municipal Airport.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 524

[Docket No. FDA-2010-N-0002]

New Animal Drugs; Mupirocin

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 Taro Pharmaceuticals U.S.A., Inc. The ANADA provides for veterinary prescription use of mupirocin ointment for the treatment of bacterial skin infections in dogs.

DATES: This rule is effective December 20, 2010.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary

Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532, filed ANADA 200-457 that provides for veterinary prescription use of Mupirocin Ointment USP, 2% for the treatment of bacterial skin infections in dogs. Taro Pharmaceuticals U.S.A., Inc.'s Mupirocin Ointment USP, 2% is approved as a generic copy of Pfizer, Inc.'s BACTODERM Ointment approved under NADA 140-839. The ANADA is approved as of November 29, 2010, and the regulations are amended in 21 CFR 524.1465 to reflect the approval.

In addition, Taro Pharmaceuticals U.S.A., Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, the tables in 21 CFR 510.600(c) are being amended to add entries for this firm.

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 Division of Dockets Management (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 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

21 CFR Part 510

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

21 CFR Part 524

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 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add an entry for "Taro Pharmaceuticals U.S.A., Inc."; and in the table in paragraph (c)(2) numerically add an entry for "051672" 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
* * *	* * *	* * *	* * *	*
Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532				051672
* * *	* * *	* * *	* * *	*
(2) * * *				
Drug labeler code	Firm name and address			
* * *	* * *	* * *	* * *	*
051672	Taro Pharmaceuticals U.S.A., Inc., 3 Skyline Dr., Hawthorne, NY 10532.			
* * *	* * *	* * *	* * *	*

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.

§ 524.1465 [Amended]

■ 4. In paragraph (b) of § 524.1465, remove "Nos. 000069 and 025463" and in its place add "Nos. 000069, 025463, and 051672".

Dated: December 10, 2010.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. 2010-31870 Filed 12-17-10; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-331F]

Schedules of Controlled Substances: Placement of 5-Methoxy-N,N-Dimethyltryptamine into Schedule I of the Controlled Substances Act

AGENCY: Drug Enforcement Administration (DEA), 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 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), including its salts, isomers and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into schedule I of the Controlled Substances Act (CSA). This action by the DEA Deputy Administrator is based on a scheduling recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and a DEA review indicating that 5-MeO-DMT meets the criteria for placement in schedule I of the CSA. This final rule will impose the criminal sanctions and regulatory controls of schedule I substances under the CSA on the manufacture, distribution, dispensing, importation, exportation, and possession of 5-MeO-DMT.

DATES: *Effective Date:* January 19, 2011.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152, Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background

In accordance with 21 U.S.C. 811(b) of the CSA, DEA gathered and reviewed the available information regarding the pharmacology, chemistry, trafficking, actual abuse, pattern of abuse, and the relative potential for abuse of 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT). On February 21, 2007, the Deputy Administrator of the DEA submitted these data to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the Deputy Administrator also requested a scientific and medical evaluation and a scheduling recommendation for 5-MeO-