

the surface of the earth are published in Paragraphs 5000 and 6002 respectively, of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed 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, when promulgated, 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).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 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 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

Paragraph 5000 Class D Airspace.

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ASO GA D Augusta, GA [Revised]

Augusta, Bush Field, GA
(Lat. 33°22'12" N, long. 81°57'52" W)

That airspace extending upward from the surface to an including 2,600 feet MSL within a 5.3-mile radius of Bush Field Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Paragraph 6002 Class E2 Airspace Designated as Surface Areas.

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ASO GA E2 Augusta, GA [Revised]

Augusta, Bush Field, GA
(Lat. 33°22'12" N, long. 81°57'52" W)

Within a 5.3-mile radius of Bush Field Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Issued in College Park, Georgia, on May 16, 2001.

Walter R. Cochran,

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

[FR Doc. 01–13310 Filed 5–25–01; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01–AEA–16]

Establishment of Class E Airspace; Coudersport, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to establish Class E airspace at Charles Cole Memorial Hospital Heliport, Coudersport, PA. Development of an Area Navigation (RNAV) Standard Instrument Approach (SIAP), Helicopter RNAV 343 approach for the Charles Cole Memorial Hospital Heliport has made this action necessary. Controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to contain aircraft executing the approach. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before June 28, 2001.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 01–AEA16, F.A.A. Eastern Region, 1

Aviation Plaza, Jamaica, NY, 11434–4809.

The official docket may be examined in the Office of the Regional Counsel, AEA–7, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY, 11434–4809; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 01–AEA–16". The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket closing both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Regional Counsel, AEA–7, F.A.A. Eastern Region, 1 Aviation Plaza, Jamaica, NY 11434–4809. Communications must identify the

notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace area at Couldersport, PA. An RNAV Approach, Helicopter RNAV 343, has been developed for Charles Cole Memorial Hospital Heliport, Couldersport, PA. Controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAP. Class E airspace designations for airspace areas extending upward from 700 feet from or above the surface are published in Paragraph 6005 of FAA Order 7400.9H, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed 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 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 would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have 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).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9H dated September 1, 2000, and effective September 16, 2000, is proposed to be amended as follows:

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

* * * * *

AEA PA E5 Couldersport, PA (New)

Charles Cole Memorial Hospital Heliport
Lat. 41°46'16.14" N/long. 77°58'28" W)

That airspace extending upward from 700 feet above the surface within a 6 mile radius of the Charles Cole Memorial Hospital Heliport.

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Issued in Jamaica, New York, on May 15, 2001.

F.D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 01-13311 Filed 5-25-01; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 96P-0460]

RIN 0910-AA01

Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would amend the final monograph for over-the-counter (OTC) topical antifungal drug products to add the ingredient clotrimazole as generally recognized as safe and effective for the treatment of athlete's foot, jock itch, and ringworm. This proposal is part of FDA's ongoing review of OTC drug products.

DATES: Submit written comments by August 27, 2001. Submit written comments on the agency's economic impact determination by August 27, 2001. See section IX of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: Submit written comments to the Docket Management Branch (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1993 (58 FR 49890), FDA published a final monograph for OTC topical antifungal drug products in part 333 (21 CFR part 333), subpart C. That monograph includes six antifungal active ingredients used for the treatment of athlete's foot, jock itch, and ringworm and one ingredient used for the prevention of athlete's foot. The monograph provides that two ingredients may contain professional labeling (may be provided to health professionals but not to the general public) for the treatment of superficial infections caused by yeast (*Candida albicans*). A manufacturer submitted a citizen petition (Refs. 1 through 4) to include the antifungal ingredient clotrimazole in the monograph for both the OTC and professional labeling treatment claims. Subsequently, the manufacturer withdrew its request to include clotrimazole in the monograph for the professional labeling treatment claim (Ref. 5).

II. The Agency's Evaluation of the Citizen Petition

A. General Background

Clotrimazole is a member of the imidazole class of antifungal drugs and is recognized in the U.S. Pharmacopeia (Ref. 6). Clotrimazole has been marketed as a topical antifungal at a 1-percent concentration in the United States as a prescription product since 1975 and as an OTC product since 1989 under new drug applications (NDAs) in cream, lotion, and solution dosage forms. The agency notes that clotrimazole has also been marketed OTC in a number of other countries, the first marketing occurring in 1980. Distribution figures (Ref. 1) indicate a significant amount of the drug has been marketed OTC in the United States and other countries since 1990. Miconazole nitrate, a related member of the imidazole class of antifungal drugs, is currently included as an active ingredient in § 333.210(c) of the final monograph for OTC topical antifungal drug products.

B. Safety

The toxicity of clotrimazole has been well-studied (Refs. 1 and 2). Acute