

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Airspace Docket No. 98-ASO-9]

#### Proposed Establishment of Class E Airspace; Villa Rica, GA

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This notice proposes to establish Class E airspace at Villa Rica, GA. A Global Positioning System (GPS) Runway (RWY) 10 Standard Instrument Approach Procedure (SIAP) has been developed for Stockmar Airport. As a result, controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAP and for Instrument Flight Rules (IFR) operations at Stockmar Airport. The operating status of the airport will change from Visual Flight Rules (VFR) to include IFR operations concurrent with the publication of the SIAP.

**DATES:** Comments must be received on or before July 20, 1998.

**ADDRESSES:** Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 98-ASO-9, Manager, Airspace Branch, ASO-520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305-5586.

**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) 305-5586.

#### 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, aeronautical, 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. 98-ASO-9." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified 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 the comments received. All comments submitted will be available for examination in the Office of the Regional Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with 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 Federal Aviation Administration, Manager, Airspace Branch, ASO-520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. 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 at Villa Rica, GA. A GPS RWY 10 SIAP has been

developed for Stockmar Airport. As a result, controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAP and for IFR operations at Stockmar Airport. The operating status of the airport will change from VFR to include IFR operations concurrent with the publication of the SIAP. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, 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. 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 7400.9D, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

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

**Spruce Creek Airport**

(Lat. 29°04'49" N, long. 81°03'27" W)

**Ormond Beach Municipal Airport**

(Lat. 29°18'04" N, long. 81°06'50" W)

That airspace extending upward from 700 feet or more above the surface of the earth within a 10-mile radius of Daytona Beach International Airport, within a 6.4-mile radius of Spruce Creek Airport and within a 7.3-mile radius of Ormond Beach Municipal Airport.

\* \* \* \* \*

Issued in College Park, Georgia, on June 10, 1998.

**Nancy B. Shelton,**

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

[FR Doc. 98-16354 Filed 6-18-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**Food and Drug Administration****21 CFR Parts 310 and 334**

[Docket No. 78N-036L]

RIN 0910-AA01

**Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening the administrative record and proposing to amend the tentative final monograph (proposed rule) for over-the-counter (OTC) laxative drug products to reclassify the stimulant laxative ingredients aloe, bisacodyl, cascara sagrada, and senna (including sennosides A and B) from Category I (generally recognized as safe and effective and not misbranded) to Category III (further testing is required). FDA is issuing this proposed rulemaking after considering data and information on the safety of bisacodyl, senna, and two related stimulant

laxative ingredients, danthron and phenolphthalein. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Submit written comments by September 17, 1998. Written comments on the agency's economic impact determination by September 17, 1998. New data by June 21, 1999. Comments on the new data by August 19, 1999.

**ADDRESSES:** Submit written comments and new data to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**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 March 21, 1975 (40 FR 12902), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC laxative, antidiarrheal, emetic, and antiemetic drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these classes. In the advance notice of proposed rulemaking, the Panel recommended Category I status for the OTC stimulant laxative ingredients aloe, bisacodyl, cascara sagrada preparations, danthron, phenolphthalein, and senna preparations (40 FR 12902 at 12908 to 12910). The agency concurred with the Panel's Category I classification of these ingredients in the tentative final monograph published in the **Federal Register** of January 15, 1985 (50 FR 2124 at 2152 to 2156).

**II. Danthron and Phenolphthalein**

In the **Federal Register** of September 2, 1997 (62 FR 46223), the agency reopened the administrative record for this rulemaking, discussed the carcinogenic risk of danthron and phenolphthalein, and proposed to reclassify these two anthraquinone laxative ingredients from Category I to Category II (not generally recognized as safe and effective or misbranded). The agency is evaluating the data and comments submitted in response to that proposal and will discuss this subject

further in a future issue of the **Federal Register**.

**III. Bisacodyl**

The FDA Center for Drug Evaluation and Research (CDER) Carcinogenicity Assessment Committee (CAC) has recommended that the anthraquinone laxatives (aloe, cascara sagrada, and senna) and bisacodyl be tested in the standard battery of genotoxicity tests and under the test conditions by which phenolphthalein was found to be positive (Ref. 1). Phenolphthalein and bisacodyl are diphenylmethane derivatives with a similar chemical structure and pharmacological characteristics. The CAC recommended the Syrian Hamster Embryo (SHE) cell transformation assay as an early screen for bisacodyl and, based on its results, either the p53 transgenic mouse assay or another in vivo alternative assay, as appropriate, follow. Two-year carcinogenicity studies would then be contingent upon the results of these assays.

The agency has informed industry that additional testing for bisacodyl will be necessary (Ref. 2). Subsequently, industry submitted data from two mutagenicity studies (Ames test and rat bone marrow micronucleus assay) and a chromosomal aberration study in Chinese hamster ovary cells. The agency has reviewed these studies and determined that the results of all of the tests were negative (Ref. 3). Phenolphthalein was tested in two of these tests and was found negative in one (Ames test). However, findings from further studies indicated that phenolphthalein presents a potential carcinogenic risk. Thus, because of the chemical similarity of bisacodyl to phenolphthalein and the lack of previous carcinogenicity testing of bisacodyl, the agency is requesting that bisacodyl undergo further testing to assess its carcinogenic potential. Industry has completed dose range finding studies intended to select bisacodyl doses for a 6-month oral gavage carcinogenicity study in the p53 transgenic mouse (Ref. 4).

**IV. Senna**

The agency has reviewed metabolic, genotoxicity, and carcinogenicity data on senna and its components (Ref. 5). Senna contains a number of components, including but not limited to: Sennosides A and B, sennosides C and D, rhein (including rhein anthrone-8-monoglucoside and rhein-8-monoglucoside), chrysophanol, emodin, and aloe-emodin. The metabolic studies show that varying amounts of senna and its metabolites are absorbed into the