

comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov> or the Superintendent of Document's Web page at <http://www.access.gpo.gov/nara>. Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA-400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, to request a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, 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 D airspace and Class E4 airspace at Ormond Beach, FL. Class D airspace designations for airspace areas extending upward from the surface of the earth and Class E airspace designations for airspace areas designated as an extension to a Class D airspace are published in Paragraphs 5000 and 6004 respectively, of FAA Order 7400.9K, dated August 30, 2002, and effective September 16, 2002, 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, 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 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 5000 Class D Airspace

* * * * *

ASO FL D Ormond Beach, FL [NEW]

Ormond Beach Municipal Airport, FL
(Lat. 29°18'04" N, long. 81°06'50" W)

That airspace extending upward from the surface, to but not including 1,200 feet MSL within a 3.2-mile radius of Ormond Beach Municipal Airport; excluding that airspace within the Daytona Beach, FL Class C airspace area. This Class D airspace area is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

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Paragraph 6004 Class E4 Airspace Areas Designated as an Extension to a Class D Airspace Area

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ASO FL E4 Ormond Beach, FL [NEW]

Ormond Beach Municipal Airport, FL
(Lat. 29°18'04" N, long. 81°06'50" W)
Ormond Beach VORTAC
(Lat. 29°18'12" N, long. 81°06'46" W)

That airspace extending upward from the surface within 2.4 miles each side of the Ormond Beach VORTAC 342° radial, extending from the 3.2-mile radius to 6.9 miles northwest of the VORTAC. This Class E4 airspace area is effective during the

specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory.

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Issued in College Park, Georgia, on July 7, 2003.

Walter R. Cochran,

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

[FR Doc. 03-18074 Filed 7-16-03; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 125 and 135

Regulatory Review—Reopen of Comment Period

AGENCY: Federal Aviation Administration

ACTION: Notice and request for comments.

SUMMARY: By this notice, the Federal Aviation Administration (FAA) reopens the comment period for its regulatory review of 14 CFR parts 135 and 125. The part 135/125 Aviation Rulemaking Committee had its first meeting on June 10-12, 2003, and members requested that the comment period be reopened to accommodate additional public comments to the docket. The FAA agrees and by this notice reopens the comment period for Docket No. FAA-2003-13923 until November 18, 2003.

DATES: The FAA will consider all comments on this regulatory review filed on or before November 18, 2003. We will consider comments filed late if it is possible to do so without incurring expense or delay.

ADDRESSES: You may submit comments to FAA-2003-13923 by any of the following methods:

- Web site: <http://dms.dot.gov>. Follow the instructions for submitting comments on the DOT electronic docket site.

- Fax: 1-202-493-2251
- Mail: Docket Management Facility: U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL-401, Washington, DC 20590-001.

- Hand Delivery: Room PL-401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 am and 5 pm, Monday through Friday, except Federal Holidays.

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the

online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number or Regulatory Identification Number (RIN) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to <http://dms.dot.gov>, including any personal information provided. Please see the Privacy Act heading under **SUPPLEMENTARY INFORMATION** and Regulatory Notices.

FOR FURTHER INFORMATION CONTACT: Katherine Perfetti, AFS-200, 800 Independence Ave. SW., Washington, DC 20591 (202) 267-3760, facsimile at (202) 267-5229, or by e-mail: Katherine.Perfetti@faa.gov.

SUPPLEMENTARY INFORMATION:

Background

By **Federal Register** notice of February 3, 2003 (68 FR 5488), the FAA announced a comprehensive regulatory review and rewrite of parts 135 and 125. It noted that issues under review may include:

a. Design and manufacture of new aircraft that current regulations do not address adequately (for example, large airships, powered lift aircraft).

b. Certain large airplanes with modifications to payload capacity and passenger seat configuration operating under part 91 or 135.

c. New equipment and technologies not adequately addressed in current regulations.

d. International harmonization, ICAO commercial standards, and increased international operations.

The FAA invited members of the public to serve on the Part 135/125 Aviation Rulemaking Committee and/or work groups by notifying the person listed in the notice before March 5, 2003. In addition, the notice solicited comments from the public to docket number FAA-2003-13923 to be filed on or before June 3, 2003.

The Part 125/135 Aviation Rulemaking Committee met on June 10-12, 2003, in Herndon, Virginia to review the docket and to assign the issues posted there to the various work groups. At the opening session of the meeting on June 10, some members requested that the docket be reopened for receiving additional public comments. The FAA agrees with the reopening of the docket and publishes this notice to advise the public of the extended

opportunity to comment on or provide any issues pertinent to this review. The reopened comment period will close on November 18, 2003, because the third meeting of the committee is planned for November 19-21, 2003.

Public Participation

The FAA invites interested parties to submit specific, detailed written comments, or provide input on issues pertinent to parts 125 and 135. All comments submitted to the docket before November 18, 2003, will be considered in the committee discussions.

Privacy Act

Anyone is able to search the electronic form of all comments received into our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Statement in the **Federal Register** published on April 11, 2000 (volume 65, Number 70, pages 19477-78), or you may visit <http://dms.dot.gov>.

Public Web Site

The FAA also reminds the public that a public Web site, <http://www.l.faa.gov/avr/arm/part135/index.cfm> has been established to provide information on the committee and the review. As part of that website, the FAA provides a list of members of the committee who may be contacted for additional information on a specific area of the review and information on future meetings of the committee.

Issued in Washington, DC on July 9, 2003.

John M. Allen,

Acting Director, Flight Standards Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

RIN 0910-AA01

External Analgesic Drug Products for Over-the-Counter Human Use; Reopening of the Administrative Record and Amendment of Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for the rulemaking for over-the-counter (OTC) external analgesic drug products to accept comments and data concerning OTC external analgesic drug products that have been filed with the Division of Dockets Management, FDA, since the administrative record officially closed. FDA is also amending the tentative final monograph (TFM) (proposed rule) to clarify the status of patch, plaster, and poultice dosage forms for OTC external analgesic drug products. FDA is providing for the administrative record to remain open for 90 days to allow for public comment on the comments and data being accepted into the rulemaking and on the status of patch, plaster, and poultice dosage forms for OTC external analgesic drug products. This action is part of FDA's ongoing review of OTC drug products.

DATES: Submit written or electronic comments and data by October 15, 2003. See section IX of this document for the effective date of any final rule that may be published based on this proposal.

ADDRESSES: Submit written comments and data to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

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

FDA has on numerous occasions received new data and information bearing on OTC drug panel reports and proposed monographs after the closing of the administrative record in a rulemaking proceeding. Under § 330.10(a)(7)(iii) (21 CFR 330.10(a)(7)(iii)), new data and information may be submitted within 12 months after publication of a TFM. Within 60 days after this 12-month period ends, comments on the new data and information may be submitted (see § 330.10(a)(7)(iv)). Under § 330.10(a)(10)(i), the administrative record closes at the end of this 60-day period.

In the **Federal Register** of February 8, 1983 (48 FR 5852), FDA published the TFM on OTC external analgesic drug products for OTC human use. The