

Total expenditures of federal financial assistance for all programs		Major federal assistance program means any program that exceeds
more than	but less than	
\$100 million	1 billion	\$3 million.
1 billion	2 billion	4 million.
2 billion	3 billion	7 million.
3 billion	4 billion	10 million.
4 billion	5 billion	13 million.
5 billion	6 billion	16 million.
6 billion	7 billion	19 million.
over 7 billion	20 million.

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 BILLING CODE 3410-90-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 95-AWP-8]

Proposed Establishment of Class E Airspace; Mammoth Lakes, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish Class E airspace at Mammoth Lakes, CA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 27 has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Mammoth Lakes Airport, Mammoth Lakes, CA.

DATES: Comments must be received on or before November 15, 1995.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, System Management Branch, AWP-530, Docket No. 95-AWP-8, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business at the Office of the Manager, System Management Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Scott Speer, Airspace Specialist, System Management Branch, AWP-530, Air

Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725-6533.

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 the comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 95-AWP-8." The postcard will be date/time stamped and returned to the commenter. All communications received on or 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 comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California 90261, 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 NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulation (14 CFR part 71) to establish Class E airspace at Mammoth Lakes, CA. The development of a GPS SIAP has made this proposal necessary. The intended effect of this proposal is to provide adequate controlled airspace for aircraft executing the GPS RWY 27 SIAP at Mammoth Lakes Airport, Mammoth Lakes, CA. Class E airspace designations are published in Paragraphs 6002 and 6005 of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in this 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 10034; 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 proposal 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).

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 is revised 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; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 6002 Class E airspace areas designated as a surface area for an airport.

* * * * *

AWP CA E2 Mammoth Lakes, CA [New]

Mammoth Lakes Airport, CA
(Lat. 37°37'26" N, long. 118°50'19" W)

Within a 4.1-mile radius of the Mammoth Lakes Airport and within 1.8 miles each side of the 099° bearing from the Mammoth Lakes Airport, extending from the 4.1-mile radius to 5.6 miles southwest of the Mammoth Lakes Airport. This Class E airspace area is effective during the specific dates and times established in advanced 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 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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AWP CA E5 Mammoth Lakes, CA [New]

Mammoth Lakes Airport, CA
(Lat. 37°37'26" N, long. 118°50'19" W)

That airspace extending upward from 700 feet above the surface within a 4.1-mile radius of the Mammoth Lakes Airport and within 1.8 miles each side of the 099° bearing from the Mammoth Lakes Airport, extending from the 4.1-mile radius to 5.6 miles southwest of the Mammoth Lakes Airport. That airspace extending upward from 1,200 feet above the surface within the area bounded by a line beginning a lat. 37°49'00" N, long. 118°58'00" W; to lat. 37°49'00" N, long. 119°13'00" W; to lat. 38°10'00" N, long. 119°13'00" W; to lat. 38°10'00" N, long.

118°34'00" W; thence to the point of beginning.

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Issued in Los Angeles, California, on October 2, 1995.

Richard R. Lien,

Manager, Air Traffic Division, Western-Pacific Region.

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BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 92P–0403]

Chlorofluorocarbon Propellants in Self-Pressurized Containers; Addition to List of Essential Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to grant the petition of Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), to add metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation to the list of products containing a chlorofluorocarbon (CFC) propellant for an essential use. Essential use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFC's in pressurized dispensers. This document proposes to amend FDA's regulations governing use of CFC's to include metered-dose albuterol sulfate and ipratropium bromide in combination for oral inhalation as an essential use.

DATES: Written comments by November 16, 1995.

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

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1049.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 2.125 (21 CFR 2.125), any food, drug, device, or cosmetic in a self-pressurized container that contains a CFC propellant for a nonessential use is

adulterated or misbranded, or both, under the Federal Food, Drug, and Cosmetic Act. This prohibition is based on scientific research indicating that CFC's may reduce the amount of ozone in the stratosphere and thereby increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation may increase the incidence of skin cancer, change the climate, and produce other adverse effects of unknown magnitude on humans, animals, and plants. Section 2.125(d) exempts from the adulteration and misbranding provisions of § 2.125(c) certain products containing CFC propellants that FDA determines provide unique health benefits that would not be available without the use of a CFC. These products are referred to in the regulation as essential uses of CFC's and are listed in § 2.125(e).

Under § 2.125(f), any person may petition the agency to request additions to the list of uses considered essential. To demonstrate that the use of a CFC is essential, the petition must be supported by an adequate showing that: (1) There are no technically feasible alternatives to the use of a CFC in the product; (2) the product provides a substantial health, environmental, or other public benefit unobtainable without the use of the CFC; and (3) the use does not involve a significant release of CFC's into the atmosphere or, if it does, the release is warranted by the consequence if the use were not permitted.

EPA regulations implementing provisions of the Clean Air Act contain a general ban on the use of CFC's in pressurized dispensers, such as metered-dose inhalers (MDI's) (40 CFR 82.64(c) and 82.66(d)). These regulations exempt from the general ban "medical devices" that FDA considers essential and that are listed in § 2.125(e). Section 601(8) of the Clean Air Act (42 U.S.C. 7671(8)) defines "medical device" as any device (as defined in the Federal Food, Drug, and Cosmetic Act), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system, if such device, product, drug, or drug delivery system uses a class I or class II ozone-depleting substance for which no safe and effective alternative has been developed (and where necessary, approved by the Commissioner of Food and Drugs (the Commissioner)); and if such device, product, drug, or drug delivery system has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator of EPA (the