(Lat. 44°15′10″ N, long. 121°18′13″ W)

Within a 5.1-mile radius of Roberts Field, and within 1.4 miles each side of the Deschutes VORTAC 269° and 089° radials extending from the 5.1-mile radius of the airport to .9 mile west of the VORTAC. 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 Seattle, Washington, on January 13, 1997.

Glenn A. Adams III,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 97–2092 Filed 1–28–97; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 96–ANM–027]

Proposed Amendment of Class E Airspace; Montrose, Colorado

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This proposed rule would amend the Montrose, Colorado, Class E airspace to accommodate a new Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to the Montrose Regional Airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before March 15, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Operations Branch, ANM–530, Federal Aviation Administration, Docket No. 96–ANM–027, 1601 Lind Avenue SW, Renton, Washington 98055–4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: James C. Frala, ANM–532.4, Federal Aviation Administration, Docket No. 96–ANM–027, 1601 Lind Avenue SW, Renton, Washington 98055–4056; telephone number: (206) 277–2535.

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. 96–ANM–027.'' 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 the light of comments received. All comments submitted will be available for examination at the address listed above 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's

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Operations Branch, ANM–530, 1601 Lind Avenue SW, Renton, Washington 98055–4056. 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 procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Montrose, Colorado, to accommodate a new GPS SIAP to the Montrose Regional Airport. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from the surface of the earth, and from 700 feet or more above the surface of the earth, are published in Paragraph 6002 and Paragraphs 6005, respectively, of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed on 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—[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; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

ANM CO E2 Montrose, CO [Revised]

Montrose Regional Airport, CO
(Lat. 38°30′32″ N, long. 107°53′38″ W)
Montrose VOR/DME
(Lat. 38°30′23″ N, long. 107°53′58″ W)

That airspace extending upward from the surface within a 4.8-mile radius of the Montrose Regional Airport, and within 3.5 miles each side of the Montrose VOR/DME 313° radial extending from the 4.8-mile radius to 12.2 miles northwest of the VOR/DME, and within 2.5 miles each side of the Montrose VOR/DME 360° radial extending from the 4.8-mile radius to 8.5 miles north of the VOR/DME. This Class E airspace area is effective during the specific dates and

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

* * * * *

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

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ANM CO E5 Montrose, CO [Revised]

Montrose Regional Airport, CO
(Lat. 38°30′32″ N, long. 107°53′38″ W)
Montrose VOR/DME
(Lat. 38°30′23″ N, long 107°53′58″ W)

That airspace extending upward from 700 feet above the surface within 4.3 miles northeast and 8.3 miles southwest of the Montrose VOR/DME 313° and 133° radials extending from 6.1 miles southeast to 21.4 miles northwest of the VOR/DME, and within 4 miles each side of the Montrose VOR/DME 360° radial extending to 9.5 miles north of the VOR/DME; and that airspace extending upward from 1,200 feet above the surface within an area bounded by a point beginning at lat. 38°40′00″ N, long. 108°46′00″ W; to lat. 38°25′00″ N, long. 108°42′30″ W; to lat. 37°58′00″ N, long. 108°10′00″ W; to lat. 38°09′00″ N, long. 107°35′00″ W; to lat. 38°43′00″ N, long. 107°39′30″ W; to lat. 38°51′30″ N, long. 107°41′00″ W; to lat. 38°50′00″ N, long. 107°53′00″ W; to lat. 38°53′00″ N, long. 108°03′30″ W; thence to the point of beginning.

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Issued in Seattle, Washington, on January 13, 1997.

Glenn A. Adams III,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 97–2093 Filed 1–28–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 601, and 606

[Docket No. 96N–0395]

Revision of the Requirements for a Responsible Head for Biological Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations by deleting the requirements for a biologics establishment to name a ''responsible head'' or ''designated qualified person'' to represent the establishment in its dealings with FDA. Because many manufacturers of biological products are firms that have more than one manufacturing location and complex corporate structures, it may no longer be practical for one individual to represent a manufacturer in all matters. The proposed rule would provide manufacturers with more flexibility in assigning control and oversight responsibility within a company. This proposed rule is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiative, and it is intended to reduce the burden of unnecessary regulations on industry without diminishing public health protection.

DATES: Comments must be submitted on or before April 29, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Corporations should submit two copies of any comments and individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 600.10(a) (21 CFR 600.10(a)), a manufacturer of biological products is required to name a ''responsible head'' who is to exercise control of the manufacturing establishment in all matters relating to compliance with regulations in parts 600 through 680 (21 CFR parts 600 through 680) and who is to represent the manufacturer in all pertinent matters with the Center for Biologics Evaluation and Research (CBER). This individual must also have an understanding of the scientific principles and techniques related to the manufacture of biological products. When FDA announced in the Federal Register of June 3, 1994 (59 FR 28821 and 28822), the review by CBER of certain biologics regulations to identify those regulations that are outdated, burdensome, inefficient, duplicative, or otherwise unsuitable or unnecessary, § 600.10(a) was included. FDA also held a public meeting on January 26, 1995, to discuss the retrospective review effort and to provide a forum for the public to voice its comments on the retrospective review.

Many of the comments submitted requested revision or elimination of the requirements for a ''responsible head'' in § 600.10(a). The majority of the comments supported deletion of the regulation. The comments stated that the requirement for a responsible head to be an expert in multiple functions and to be responsible for a number of facility locations is incompatible with current industry practice. The comments added that the list of activities in § 600.10(a) is extremely broad and this regulation could be interpreted to require the responsible head to have an intimate understanding of a wide variety of extremely complex activities. All of these activities require specific expertise, and it may not be practical to expect one person to be an expert in all of those areas. Some comments addressed the requirement that the responsible head be responsible for training and have the authority to enforce discipline, stating that direct line supervision and management personnel are much better qualified and in a better position to ''enforce or direct the enforcement of discipline and performance of assigned functions by employees engaged in the manufacture of products.'' Many comments requested the designation of an alternate responsible head, especially in the situation of multiple locations.

As part of the President's ''Reinventing Government'' initiative, a report entitled ''Reinventing the Regulation of Drugs Made From Biotechnology'' was issued in November 1995. The report announced several initiatives to reduce the burden of FDA regulations on the biologics industry without reducing public health protection, including a proposal to remove the requirements in § 600.10(a) for a ''responsible head.'' The proposed revision, reflecting comments submitted in response to the January 26, 1995, public meeting, would enable firms to designate more than one person to communicate directly with FDA on official matters related to the biological products they manufacture. The commitment to remove requirements for a ''responsible head'' was based on FDA's determination that, with the many changes that have occurred in science, technology, and corporate structure, it no longer may be practical for most biologics manufacturers to rely on one individual to meet the requirements included in § 600.10(a). In addition, the responsible corporate officer doctrine, e.g., *United States* v. *Park*, 421 U.S. 658 (1975); *United States* v. *Dotterweich*, 320 U.S. 277 (1943),