Larry Tonish, Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6531.

SUPPLEMENTARY INFORMATION:

History

On June 9, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by amending the Class E airspace areas at Mammoth Lakes, CA (62 FR 31374). The development of a GPS SIAP at Mammoth Lakes Airport has made this action necessary. The intended effect of this action is to provide adequate airspace for aircraft executing the GPS RWY 27 SIAP to Mammoth Lakes Airport, Mammoth Lakes, CA.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1. Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) amends the Class E airspace area at Mammoth Lakes, CA. The development of a GPS SIAP at Mammoth Lakes Airport has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for aircraft executing the GPS RWY 27 SIAP at Mammoth Lakes Airport, Mammoth Lakes, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this 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 will only affect air traffic procedures and air navigation, it is certified that this 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).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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 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 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Mammoth Lakes, CA [Revised]

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 6.6-mile radius 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. 119°00′00″ W; to lat. 37°49′00″ N, long. 119°13′00″ W; to lat. 38°11′00″ N, long. 119°13′00″ W; to lat. 38°11′00″ N, long. 118°27′00″ W; to lat. 37°30′00″ N, long. 118°27′00″ W; to lat. 37°30′00″ N, 119°00′00″ W, thence to the point of beginning.

* * * * *

Issued in Los Angeles, California, on August 12, 1997.

Sonja P. Keller,

Acting Manager, Air Traffic Division Western-Pacific Region.

[FR Doc. 97–23604 Filed 9–4–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–11]

Establishment of Class E Airspace; Sebastian, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes Class E airspace at Sebastian, FL. A Global Positioning System (GPS) Runway (RWY) 4 Standard Instrument Approach Procedure (SIAP) has been developed for Sebastian Municipal Airport. 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 the airport. The operating status of the airport will change from Visual Flight Rules (VFR) to include IFR operations concurrent with publication of the SIAP.

EFFECTIVE DATE: 0901 UTC, November 6, 1997.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5581.

SUPPLEMENTARY INFORMATION:

History

On May 14, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) by establishing Class E airspace at Sebastian, FL, (62 FR 26458). This action will provide adequate Class E airspace for IFR operations at Sebastian Municipal Airport. Designations for Class E airspace extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9D dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in CFR part 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Sebastian, FL, to accommodate a GPS RWY 4 SIAP and for IFR operations at Sebastian Municipal Airport. The operating status of the airport will be changed from VFR to include IFR operations concurrent with publication of the SIAP.

The FAA has determined that this 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 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).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 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, EO 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 4, 1996, and effective September 16, 1996, is amended as follows:

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

* * * * *

ASO FL E5 Sebastian, FL [New]

Sebastian Municipal Airport, FL
(Lat. 27°48′46″ N, long. 80°29′44″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Sebastian Municipal Airport, excluding that airspace within the Vero Beach, FL, Class E airspace area.

* * * * *

Issued in College Park, Georgia, on August 6, 1997.

Nancy B. Shelton,

Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–23603 Filed 9–4–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 95N–0138]

Disqualification of a Clinical Investigator

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the investigational new drug regulation that provides for disqualification of clinical investigators who submit false information. The revision is intended to clarify the agency's authority to reach sponsor-investigators under the regulation.

EFFECTIVE DATE: November 4, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is amending the regulations governing the disqualification of clinical investigators to clarify that § 312.70 (21 CFR 312.70) reaches sponsor-investigators.

Part 312 (21 CFR part 312) requires sponsors to monitor the progress of clinical investigations, to review and evaluate evidence relating to the safety and effectiveness of the drug under investigation, and to report to FDA information based on these monitoring and review activities. Clinical investigators conduct clinical trials on new drugs and submit the resulting data to individual or corporate sponsors. Data generated by the clinical investigators are the subject of the reports submitted by sponsors to FDA.

In the **Federal Register** of February 16, 1996 (61 FR 6177), FDA proposed amending § 312.70 by adding language that would clarify that FDA can disqualify clinical investigators, including sponsor-investigators, for submitting to sponsors or to FDA false information in any required report. Under current § 312.70(b), the agency may disqualify an investigator who has ''deliberately or repeatedly submitted false information to the sponsor in any required report.'' However, unlike investigators, sponsor-investigators, who both directly conduct investigations and report data to FDA, submit information directly to FDA and not to a separate sponsor. Because § 312.3(b) specifically states that the ''requirements applicable to a sponsor-investigator under this part include both those applicable to an investigator and a sponsor,'' § 312.70(b) encompasses the disqualification of sponsor-investigators. This has been the agency's long-standing interpretation for clinical investigator disqualifications for drugs, animal drugs, and devices. However, for clarity, the agency is amending this regulation to make specific reference to FDA and to sponsor-investigators. FDA also intends in the near future to review and harmonize the clinical investigator disqualification provisions under device and animal drug regulations (21 CFR 812.119 and 511.1(c)) with the changes made in this final rule.

II. Comments on the Proposed Rule

FDA received one comment on the proposed rule. The comment commended FDA for the proposed amendment to § 312.70, stating that it is imperative that data supporting the safety and efficacy of pharmaceuticals be accurate and reliable. The comment noted that it was in the best interest of patients, investigators, pharmaceutical companies, and the Government that FDA be able to assure the integrity of data. The comment also expressed support for the disqualification of a clinical investigator who has deliberately or repeatedly supplied false information to a sponsor or to FDA.

FDA welcomes comments and suggestions from all persons interested in protecting the integrity of clinical data. The deliberate submission of false information by those directly responsible for administering or dispensing an investigational new drug subverts the integrity of the review process. At worst, such actions may endanger public health and safety and, at a minimum, will challenge public confidence in a review process that is conducted with honesty by the vast majority of investigators and sponsor-investigators.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866