§ 71.1 [Amended]

n 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

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

* * * * *

AWP AZ E5 Marana Regional, AZ [New]

Marana Regional, AZ
(Lat. 32°24′34″ N, long. 111°13′06″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Marana Regional, excluding that portion within the Tucson Class E airspace area.

* * * * *

Issued in Los Angeles, California, on July 29, 2005.

John Clancy,

Area Director, Western Terminal Operations.

[FR Doc. 05–16926 Filed 8–24–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–22160; Airspace Docket No. 2005–ASW–12]

Modification to Class E Airspace; Ruidoso, NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action modifies the Class E airspace area at Santa Elena, TX to provide adequate controlled airspace for the Instrument Landing System (ILS) standard instrument approach procedure (SIAP) at the Sierra Blanca Regional Airport (SRR).

DATES: Effective 0901 UTC, October 27, 2005.

Comments for inclusion in the Rules Docket must be received on or before September 27, 2005.

ADDRESSES: Send comments on the rule to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20490–0001. You must identify the docket number, FAA–2005–22160/Airspace Docket No. 2004–ASW–12, at the beginning of your comments. You may also submit comments on the Internet at the DOT docket Web site, *http://dms.dot.gov* or the government-wide Web site, *http://www.regulations.gov*. Anyone can find and read the comments received in this docket, including the name, address and any other personal information placed in the docket by a commenter. You may hand deliver your comments and review the public docket containing any comments received and this direct final rule in person at the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is located on the plaza level of the Department of Transportation NASSIF Building at the street address stated previously.

An informal docket may also be examined during normal business hours at the office of the Air Traffic Division, Airspace Branch, Federal Aviation Administration, Southwest Region, 2601 Meacham Boulevard, Fort Worth, TX. Call the manager, Airspace Branch, ASW–520, telephone (817) 222–5520; fax (718) 222–5981, to make arrangements for your visit.

FOR FURTHER INFORMATION CONTACT: Joseph R. Yadouga, Air Traffic Division, Airspace Branch, Federal Aviation Administration, Southwest Region, Fort Worth, TX 76193–0520; telephone: (817) 222–5597.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR part 71 modifies the Class E airspace area extending upward from 700 feet above the surface of Ruidoso, NM in conjunction with the Sierra Blanca Regional Airport for which a new standard instrument approach has been prescribed and will be published in paragraph 6005 of FAA Order 7400.9M, dated August 30, 2004, and effective September 16, 2004, which is incorporated by reference in 14 CFR 71.1.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in an adverse or negative comment, and, therefore, issues it as a direct final rule. 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. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of an intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a direct final rule, and was not preceded by a notice of proposed rulemaking, interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications must identify both docket numbers. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Agency Findings

This rule does not have federalism implications, as defined in Executive Order No. 13132, because it does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this rule.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) does not

warrant preparation of a Regulatory Evaluation as these routine matters will only affect air traffic procedures and air navigation. I certify 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.

Authority for This Rulemaking

The FAA authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103, ''Sovereignty and use of airspace.'' Under that section, the FAA is charged with developing plans and policy for the use of the navigable airspace and assigning by regulation or order the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. The FAA may modify or revoke an assignment when required in the public interest. This regulation is within the scope of that authority because it is in the public interest to provide greater control of the airspace for the safety of aircraft operating in the vicinity of the newly established standard instrument approach procedure.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

n Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (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

n 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]

n 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9M, Airspace Designations and Reporting Points, dated August 30, 2004, and effective September 16, 2004, is amended as follows:

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

ASW NM E5 Ruidoso, NM [Revised]

Sierra Blanca Regional Airport, NM
Lat. 33°27′46.30″ N, Long. 105°32′05.10″ W

That airspace extending upward from 700 feet above the surface within a 7.1-mile radius of the Sierra Blanca Airport and within 4 miles each side of the 241° bearing from the airport extending from 7.1-mile radius to 20.60 miles northeast of the Sierra Blanca Regional Airport.

* * * * *

Issued in Fort Worth, TX, on August 18, 2005.

Samuel J. Gill, Jr.,

Acting Area Director, Central En Route and Oceanic Operations.

[FR Doc. 05–16925 Filed 8–24–05; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2004N–0194]

Definition of Primary Mode of Action of a Combination Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its combination product regulations to define ''mode of action'' (MOA) and ''primary mode of action'' (PMOA). Along with these definitions, the final rule sets forth an algorithm the agency will use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product. Finally, the final rule will require a sponsor to base its recommendation of the agency component with primary jurisdiction for regulatory oversight of its combination product by using the PMOA definition and, if appropriate, the assignment algorithm. The final rule is intended to promote the public health by codifying the agency's criteria for the assignment of combination products in transparent, consistent, and predictable terms.

DATES: The regulation is effective November 23, 2005.

FOR FURTHER INFORMATION CONTACT: Leigh Hayes, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of May 7, 2004 (69 FR 25527), FDA published a proposed rule that proposed to define ''mode of action'' (MOA) and ''primary mode of action'' (PMOA) (the proposed rule). Along with these definitions, the proposal set forth an algorithm the agency proposed to use to assign combination products to an agency component for regulatory oversight when the agency cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product. Finally, the proposal put forth a requirement that a sponsor make its recommendation of the agency component with primary jurisdiction for regulatory oversight of its combination product by using the PMOA definition and, if appropriate, the assignment algorithm.

As set forth in part 3 (21 CFR part 3), and as described in the proposed rule, a combination product is a product comprised of any combination of a drug and a device; a device and a biological product; a biological product and a drug; or a drug, a device, and a biological product. A combination product includes: (1) A product comprised of two or more regulated components, i.e., drug/device, biological product/device, drug/biological product, or drug/device/biological product, that are physically, chemically, or otherwise combined or mixed and produced as a single entity; (2) two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products; (3) a drug, device, or biological product packaged separately that, according to its investigational plan or proposed labeling, is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or (4) any investigational drug, device, or