

levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

### **PART 39—AIRWORTHINESS DIRECTIVES**

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

#### **§ 39.13 [Amended]**

2. Section 39.13 is amended by adding the following new airworthiness directive:

97-06-07 Dornier: Amendment 39-9964.

Docket 96-NM-117-AD.

*Applicability:* Model 328-100 series airplanes equipped with Burns Aerospace Corporation commuter seat models JB6.8-1-22 and JB6.8-2-42 passenger seats; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not

been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent failure of the anchor point fasteners on the seat restraining systems, which could result in release of the seat restraint and consequent injury to passengers, accomplish the following:

(a) Within 60 days after the effective date of this AD, replace each anchor point fastener on the restraining system of each seat with a fastener of improved design, in accordance with Dornier Service Bulletin SB-328-25-114, dated July 10, 1995.

Note 2: The Dornier service bulletin references Burns Aerospace Corporation Service Bulletin SB-25-20-989, Revision B, dated June 14, 1995, as an additional source of procedural service information for replacement of the anchor point fasteners.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The replacement shall be done in accordance with Dornier Service Bulletin SB-328-25-114, dated July 10, 1995. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Dornier Luftfahrt GmbH, P.O. Box 1103, D-82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on April 18, 1997.

Issued in Renton, Washington, on March 6, 1997.

Neil D. Schalekamp,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*  
[FR Doc. 97-6262 Filed 3-13-97; 8:45 am]

**BILLING CODE 4910-13-U**

### **14 CFR Part 71**

[Airspace Docket No. 96-ASW-20]

### **Revision of Class E Airspace; Gallup, NM**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This action revises the Class E airspace extending upward from 700 feet above ground level (AGL) at Gallup, NM. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 24 at Gallup Municipal Airport has made this action necessary. This action is intended to provide adequate Class E airspace to contain instrument flight rule (IFR) operations for aircraft executing the GPS SIAP to RWY 24 at Gallup Municipal Airport, Gallup, NM.

**EFFECTIVE DATE:** 0901 UTC, May 22, 1997.

**FOR FURTHER INFORMATION CONTACT:** Donald J. Day, Operations Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0530, telephone 817-222-5593.

#### **SUPPLEMENTARY INFORMATION:**

##### **History**

On November 22, 1996, a proposal to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the Class E airspace at Gallup, NM, was published in the Federal Register (61 FR 59383). A GPS SIAP to RWY 24 developed for Gallup Municipal Airport, Gallup NM, requires the revision of the Class E airspace at this airport. The proposal was to revise the controlled airspace extending upward from 700 feet AGL to contain IFR operations in controlled airspace during portions of the terminal operation and while transitioning between the enroute and terminal environments.

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. The rule is adopted as proposed.

The coordinates for this airspace docket are based on North American Datum 83. Class E airspace designations for airspace areas extending upward from 700 feet or more AGL 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. The Class E airspace designation

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 located at Gallup Municipal Airport, Gallup, NM, to provide controlled airspace extending upward from 700 feet AGL for aircraft executing the GPS SIAP to RWY 24.

The FAA has determined that this regulation only involves an established body of technical regulations that need frequent and routine amendments 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 11035; 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 Subject 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. 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 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 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

ASW NM E5 Gallup, NM [Revised]

Gallup Municipal Airport, NM

(Lat 35°30'40"N., long 108°47'22"W.)

Gallup VORTAC

(Lat. 35°28'34"N., long 108°52'21"W.)

Gallup ILS Localizer

(Lat 35°30'53"N., long 108°46'28"W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of Gallup Municipal Airport and within 1.9 miles each side of the Gallup ILS Localizer southwest course extending from the 6.7-mile radius to 12.6 miles southwest of the airport and within 2 miles each side of the 074° bearing from the airport extending from the 6.7-mile radius to 9.1 miles east of the airport and within 1.3 miles each side of the 242° radial of the Gallup VORTAC extending from the 6.7-mile radius to 11.5 miles southwest of the airport and that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at lat 35°47'30"N, long 108°34'02"W; to lat 35°26'50"N, long 108°34'02"W; to lat 35°13'15"N, long 109°06'02"W to lat 35°20'25"N, long 109°10'42"W; to lat 35°52'00"N, long 108°47'02"W; to point of beginning excluding that airspace within the New Mexico, NM, Class E airspace area.

\* \* \* \* \*

Issued in Fort Worth, TX, on March 7, 1997.

Albert L. Viselli,

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

[FR Doc. 97-6529 Filed 3-13-97; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 200, 250, and 310

[Docket No. 96N-0183]

RIN 0910-AA53

#### Consolidation of Drug Regulations

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is consolidating a list of drugs, previously determined by rulemaking to be new drugs, into one section. This document also removes the sections now providing for these drugs, except for certain information in the regulations that FDA considers to be necessary. This action, which will make the regulations more concise and efficient, is being taken in response to the President's regulatory reinvention initiative (REGO).

**EFFECTIVE DATE:** April 14, 1997.

#### FOR FURTHER INFORMATION CONTACT:

Mary E. Catchings, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-7), 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On March 4, 1995, President Clinton issued a memorandum titled “Regulatory Reinvention Initiative,” which directed all Federal agencies to conduct a page-by-page review of their existing regulations and to “eliminate or revise those that are outdated or otherwise in need of reform.” As a result of that review and as part of its response to the President's directive, FDA published a document in the Federal Register of June 11, 1996 (61 FR 29502), proposing to amend those parts of its drug regulations codified in parts 200, 250, and 310 (21 CFR parts 200, 250, and 310), regarding certain drugs determined by rulemaking to be new drugs.

FDA proposed the following: (1) To revise § 310.502 to consolidate into one section a list of drugs (now codified in parts 200, 250, and 310) that have been determined by rulemaking procedures to be new drugs requiring approved new drug applications, and (2) to remove those sections in parts 200, 250, and 310 now providing for those drugs, except for certain information in § 310.509 that FDA considers to be necessary. The agency received no comments in response to the proposal to amend or remove these regulations.

##### II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.