DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Amended]

(14 CFR) Part 71 by

Amendment of Class D and Class E airspace; Twentynine Palms, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: This action amends Class D and Class E airspace at Twentynine Palms SELF Airport, Twentynine Palms, CA. This action changes the airport name formerly called Twentynine Palms Expeditionary Air Field (EAF), Marine Corps Base. This action also adjusts the geographic coordinates of the airport to enhance the safety and management of aircraft operations at Twentynine Palms SELF Airport, Twentynine Palms, CA. This action does not change the boundaries of the airspace.

DATES: Effective date, 0901 UTC, March 7, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203–4537.

SUPPLEMENTARY INFORMATION:

History

The FAA’s Aeronautical Products Office requested the change to the airport name and geographic coordinates of Twentynine Palms SELF Airport, Twentynine Palms, CA. The Class D airspace and Class E airspace designations are published in paragraph 5000 of Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Twentynine Palms SELF Airport, Twentynine Palms, CA.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, “Environmental Impacts: Policies and Procedures,” paragraph 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists 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—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:


§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012, is amended as follows:

Paragraph 5000 Class D airspace.

AWP CA D Twentynine Palms, CA [Amended]

Twentynine Palms SELF Airport, CA (Lat. 34°17′46″ N., long. 116°09′44″ W.)

That airspace extending upward from the surface to and including 4,600 feet MSL within a 4.3-mile radius of the Twentynine Palms SELF Airport. This Class D 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.

Paragraph 6004 Class E airspace designated as an extension to a Class D surface area.

AWP CA E4 Twentynine Palms, CA [Amended]

Twentynine Palms SELF Airport, CA (Lat. 34°17′46″ N., long. 116°09′44″ W.)

That airspace extending upward from the surface within 1.8 miles each side of the Twentynine Palms VORTAC 298° radial extending from the 4.3-mile radius of Twentynine Palms SELF Airport to 13.9 miles 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.
I. Background

A. Rationale for the Rulemaking

As set forth in part 3 (21 CFR part 3), 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. Under § 3.2(e), a combination product includes:

1. A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity (single-entity combination products);

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 (co-packaged combination 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 (a type of cross-labeled combination product).

E. How To Comply With Drug CGMP Requirements Under § 4.4(b)(2)

F. How To Comply With Biological Product and HCT/P Requirements Under § 4.4(b)(3)

G. Enforcement and Effective Date

H. Guidance

I. Other

III. Legal Authority

IV. Analysis of Economic Impacts

A. Introduction

B. Rationale for Final Rule

C. Response to Comments

D. Impact of Final Rule

E.3. How To Comply With Biological Product and HCT/P Requirements Under § 4.4(b)(2)

E.2. How To Comply With Drug CGMP Requirements Under § 4.4(b)(1)

For purposes of part 3 and this rule, a “biological product” means a biological product subject to regulation under section 351 of the Public Health Service Act (42 U.S.C. 262). All biological products regulated under the PHS Act meet the definitions of drug or device in section 201 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321).