DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket FAA No. FAA—2012–1253; Airspace Docket No. 12–AWP–10]

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 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 paragraphs 5000 and 6004, respectively, of FAA Order 7400.9W, dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The Class D airspace and Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

The FAA amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by changing the airport name described in Class D airspace and Class E airspace designated as an extension to Class D surface area at Twentynine Palms, CA, to Twentynine Palms SELF Airport.

The FAA has determined 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

§ 71.1 [Amended]

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

AWP CA E4 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.
DEPARTMENT OF HEALTH AND 
HUMAN SERVICES 

Food and Drug Administration 

21 CFR Part 4 
[Docket No. FDA–2009–N–0435] 

Current Good Manufacturing Practice Requirements for Combination Products 

AGENCY: Food and Drug Administration, HHS. 

ACTION: Final rule. 

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this regulation on the current good manufacturing practice (CGMP) requirements applicable to combination products. This rule is intended to promote the public health by clarifying which CGMP requirements apply when drugs, devices, and biological products are combined to create combination products. In addition, the rule sets forth a transparent and streamlined regulatory framework for firms to use when demonstrating compliance with CGMP requirements for "single-entity" and "co-packaged" combination products. 

DATES: This rule is effective July 22, 2013. 

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130, Silver Spring, MD 20993, 301–796–8930. 

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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 (the PHS 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).