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 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, formerly Twentynine Palms Expeditionary Air Field (EAF), Marine Corps Base. The geographic coordinates of the airport are also adjusted to be in accordance with the FAA's aeronautical database. Accordingly, since this is an administrative change and does not involve a change in the dimensions or operation requirements of that airspace, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined 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 this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106, describes the authority for 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. 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:

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 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.

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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.

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AWP CA E4 Twentynine Palms, CA [Amended]

Twentynine Palms SELF Airport, CA
(Lat. 34°17′46″ N., long. 116°09′44″ W.)
Twentynine Palms VORTAC
(Lat. 34°06′44″ N., long. 115°46′12″ 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.

Issued in Seattle, Washington, on December 19, 2012.

Clark Desing,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2013–01071 Filed 1–18–13; 8:45 am]

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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.

SUPPLEMENTARY INFORMATION:

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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.[1] 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); or

4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect (another type of cross-labeled combination product).

The constituent parts of a combination product retain their regulatory status (as a drug or device, for example) after they are combined. Accordingly, the CGMP requirements that apply to each of the constituent parts continue to apply when they are combined to make combination products.[2] To date, however, the Agency has not issued specific regulations clarifying the applicability of the CGMP requirements to combination products. While CGMP regulations are in place that establish requirements for drugs, devices, and biological products, there are currently no regulations that clarify and explain the application of these CGMP requirements when these drugs, devices, and biological products are constituent parts of a combination product. FDA believes that the absence of clear CGMP requirements for combination products could result in inconsistent or differing application of the various CGMP requirements applicable to the constituent parts, which could affect product safety and the public health. In addition, the absence of clear requirements could lead some manufacturers to develop and document manufacturing practices that are redundant and overly burdensome.

In the **Federal Register** of October 4, 2004 (69 FR 59239), the Agency announced the availability of a Draft Guidance for Industry and FDA entitled ''Current Good Manufacturing Practices for Combination Products.'' The Agency received 15 comments, which were largely supportive of the regulatory approach described in the draft guidance. A common theme that emerged from these comments was the need to develop a clear regulatory framework that takes account of the fact that combination products are made up of drug, device, and biological product constituent parts. At the same time, commenters wanted to ensure that the framework would not lead to unnecessary redundancy in the operating systems used to meet CGMP

[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 (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).

[2] Section 501 of the FD&C Act (21 U.S.C. 351) states circumstances under which drugs and devices (including biological products, which also meet the definition of either drug or device) are deemed adulterated. Adulteration includes the failure to manufacture a product in accordance with applicable CGMP requirements, regardless of whether the product appears to meet its final specifications. See, generally, 21 U.S.C. 351(a)(2)(B) and (h).