

geographic lat./long. coordinate for the point located in the northeast corner of R-2603 has been relocated, so as to not impact use of the airway.

### The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 73 to establish a new restricted area R-2603 at the Pinon Canyon Maneuver Site, near Trinidad, CO. The FAA is also incorporating the restricted area updates noted in the Differences from the NPRM section. The FAA is taking this action to ensure realistic Army training which provides increased ground-to-air, air-to-ground, and air-to-air battle space to increase training capacity and relieve training congestion at Fort Carson. The changes from what was proposed in the NPRM are as follows:

*R-2603:* The geographic coordinate proposed as “lat. 37°38’33” N., long. 103°35’11” W.” in the boundaries description is deleted and replaced by a point identified as “lat. 37°38’28” N., long. 103°42’40” W.” The legal description of R-2603 was changed from a counter clockwise direction to a clockwise direction.

### Regulatory Notices and Analyses

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. It, therefore: (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 the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### Environmental Review

The FAA has determined that this action of establishing restricted area R-2603 within the existing Fort Carson, CO, Pinon Canyon Maneuver Site (PCMS), near Trinidad, CO, qualifies for FAA adoption in accordance with FAA Order 1050.1F, paragraphs 8–2 and 9–2, *Adoption of Other Agencies’ National Environmental Policy Act Documents, and Written Re-evaluations*, and 7400.2L, paragraph 32–2–3. The purpose of creating and utilizing the Restricted Area (RA) is to allow for

increased ground-to-air, air-to-ground, and air-to-air battle space to increase training capacity and relieve training congestion at Fort Carson. The FAA, after conducting an independent review and evaluation of the United States Army’s Final Environmental Impact Statement of the Pinon Canyon Maneuver Site Training and Operations (EIS) and Record of Decision (ROD) for Restricted Area R-2603 at Fort Carson, CO, has determined that the Army’s EIS and its supporting documentation adequately assesses and discloses the environmental impacts of the Proposed Action including evaluation of the establishment of airspace for restricted airspace area R-2603. In March 2013, the Army Environmental Command and Fort Carson released the EIS regarding the Pinon Canyon Maneuver Site (PCMS) Training and Operations located in Colorado. On May 1, 2015, the Army issued their ROD. The Army prepared its EIS and ROD in compliance with NEPA and Army-specific environmental regulations (32 CFR part 651).

Based on the evaluation for potential environmental impact in the Army’s EIS, the FAA, as the Cooperating Agency for the Army’s proposed action, concluded that adoption of the Army’s EIS evaluating the proposed establishment of R-2603 is authorized in accordance with 40 CFR 1506.3, *Adoption*. Accordingly, FAA adopts the Army’s EIS and takes full responsibility for the scope and content that address the FAA’s airspace establishment action.

### List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

### The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

### PART 73—SPECIAL USE AIRSPACE

- 1. The authority citation for part 73 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### § 73.26 [Amended]

- 2. Section 73.26 is amended as follows:

\* \* \* \* \*

#### R-2603 Fort Carson, CO [New]

**Boundaries:** Beginning lat. 37°22’30” N., long. 104°04’47” W.; to lat. 37°32’27” N., long. 104°06’32” W.; to lat. 37°32’27” N., long. 104°02’15” W.; to lat. 37°33’21” N., long. 103°57’55” W.; to lat. 37°35’59” N., long. 103°57’50” W.; to lat. 37°35’57” N.,

long. 103°54’40” W.; to lat. 37°38’10” N., long. 103°48’47” W.; to lat. 37°38’32” N., long. 103°48’43” W.; to lat. 37°38’28” N., long. 103°42’40” W.; to lat. 37°32’46” N., long. 103°42’46” W.; to lat. 37°21’10” N., long. 103°54’41” W.; to lat. 37°21’15” N., long. 104°02’35” W.; thence to the point of beginning.

**Designated altitudes:** Surface to but not including 10,000 feet Mean Sea Level (MSL).

**Time of designation:** By NOTAM 24 hours in advance.

**Controlling agency:** FAA, Denver ARTCC.

**Using agency:** Commander, U.S. Army, Fort Carson, CO.

Issued in Washington, DC, on October 3, 2017.

**Scott M. Rosenbloom,**

*Acting Manager, Airspace Policy Group.*

[FR Doc. 2017–21794 Filed 10–6–17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 870

[Docket No. FDA–2017–N–1620]

#### Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Cardiovascular Status Indicator; Correction

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

**ACTION:** Final order; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final order entitled “Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Cardiovascular Status Indicator” that appeared in the **Federal Register** of July 28, 2017. The final order was published with an incorrect statement in the preamble about whether FDA planned to exempt the device from premarket notification requirements. This document corrects that error.

**DATES:** Effective October 10, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Nathalie Yarkony, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1254, Silver Spring, MD 20993–0002, [Nathalie.yarkony@fda.hhs.gov](mailto:Nathalie.yarkony@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 28, 2017 (82 FR 35065), FDA published the final order “Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Cardiovascular Status Indicator.” The final order published with an incorrect statement in the preamble about

whether FDA planned to exempt the device from premarket notification requirements under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)).

#### Correction

In the **Federal Register** of July 28, 2017, in FR Doc. 2017-15901, the following correction is made:

On page 35066, at the bottom of the page below table 1, beginning in the first column, the third paragraph is corrected as follows:

“Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the adjunctive cardiovascular status indicator they intend to market.”

Dated: October 2, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-21659 Filed 10-6-17; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2017-0792]

RIN 1625-AA00

#### Safety Zone; Atlantic Intracoastal Waterway, Camp Lejeune, NC

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the Atlantic Intracoastal Waterway in Camp Lejeune, North Carolina in support of military training exercises. This temporary safety zone is intended to restrict vessel traffic from a portion of the Atlantic Intracoastal Waterway between Mile Hammock Bay and Onslow Beach Swing Bridge during military training operations. This action

is intended to restrict vessel traffic on the Atlantic Intracoastal Waterway to protect mariners, vessels, and training exercise participants from the hazards associated with military training operations. Entry of vessels or persons into this safety zone is prohibited unless specifically authorized by the Captain of the Port (COTP) North Carolina or a designated representative.

**DATES:** This rule is effective from October 10, 2017 through October 30, 2017.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-0792 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, contact Petty Officer Matthew Tyson, Waterways Management Division, U.S. Coast Guard Sector North Carolina, Wilmington, NC; telephone: 910-772-2221, email: [Matthew.I.Tyson@uscg.mil](mailto:Matthew.I.Tyson@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### I. Table of Abbreviations

CFR Code of Federal Regulations  
COTP Captain of the Port  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code  
ICW IntraCoastal Waterway

##### II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The Coast Guard was notified of the final dates needed for this rule on August 17, 2017. It is impracticable and contrary to the public interest to delay this action. Waiting for a comment period to run would inhibit the Coast Guards’ ability to protect the public and participants from the dangers associated with the military exercises scheduled from October 10 through October 30, 2017.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. Immediate implementation is required to protect the public and participants from the dangers associated with the military training exercises.

##### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231. The COTP North Carolina has determined that potential hazards associated with the military exercises scheduled from October 10 through October 30, 2017, is a safety concern for mariners and participants. The military training exercises involve building temporary bridges, crossing with amphibious vehicles, and other military operations on the ICW. These military training activities will block the waterway in a manner that restricts all vessel navigation and movement within this segment of the ICW. This rule is necessary to protect persons and vessels from the potential hazards associated with the military training exercises.

##### IV. Discussion of the Rule

The safety zone will be enforced on the following dates and times in October 2017:

Date	Time
10th–12th .....	8 a.m. through 11 a.m. and 1 p.m. through 4 p.m.
13th .....	9 a.m. through 12 p.m. and 1 p.m. through 4 p.m.
18th .....	8 a.m. through 12 p.m.
24th .....	8 a.m. through 12 p.m. and 1 p.m. through 4 p.m.
25th–26th .....	9 a.m. through 1 p.m. and 2 p.m. through 5 p.m.
27th–28th .....	7 a.m. through 5 p.m.
29th–30th .....	7 a.m. through 11 a.m.

The safety zone will include all navigable waters of the ICW from Mile Hammock Bay, approximate position 34°32′46″ N., 77°19′17″ W., to Onslow Beach Swing Bridge approximate position 34°34′25″ N., 77°16′14″ W. (NAD 1983), an approximately four mile portion of the ICW. The duration of this zone is intended to protect mariners from the hazards associated with military training operations. No vessel or person will be permitted to enter the safety zone unless specifically authorized by the Captain of the Port North Carolina or a designated representative. The regulatory text appears at the end of this document.