

obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes, "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at [www.fda.gov/cdrh](http://www.fda.gov/cdrh).

#### V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VI. 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 (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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. Because this rule will relieve a burden and simplify the marketing of these devices, the agency 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.

#### VII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

#### List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

#### PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.5440 is amended by revising paragraph (b) to read as follows:

#### § 880.5440 Intravascular administration set.

\* \* \* \* \*

(b) *Classification.* Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled "Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers." Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

Dated: March 12, 2001.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

[FR Doc. 01–6938 Filed 3–20–01; 8:45 am]

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#### DEPARTMENT OF TRANSPORTATION

#### Coast Guard

#### 33 CFR Part 165

[COTP Western Alaska–01–001]

RIN 2115–AA97

#### Safety Zone; Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, AK

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule; Correction.

**SUMMARY:** The Coast Guard published in the **Federal Register** of March 19, 2001, a document establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska. The effective date of the safety zone has changed from March 23, 2001 to March 22, 2001. This correction changes that date.

**DATES:** This temporary final rule is effective on March 22, 2001.

**ADDRESSES:** The public docket for this rulemaking is maintained by Coast Guard Marine Safety Office Anchorage, 510 "L" Street, Suite 100, Anchorage, AK 99501. Materials in the public docket are available for inspection and copying at Coast Guard Marine Safety Office Anchorage. Normal office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LCDR Rick Rodriguez, Marine Safety Office Anchorage, at (907) 271–6700.

**SUPPLEMENTARY INFORMATION:** The Coast Guard published a document, in the **Federal Register** of March 19, 2001 (66 FR 15350) establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska, effective March 23, 2001. The effective date has changed to March 22, 2001 due to a late revision of the rocket launch date. This correction changes the beginning effective date of March 23, 2001 to March 22, 2001.

#### § 165.T17–012 [Corrected]

In rule FR Document 01–6740 published on March 19, 2001 (66 FR 15350) make the following corrections. On page 15350, in the 2nd column under *Background and Purpose*, remove the date "March 23, 2001" and add the

date "March 22, 2001". On page 15350, in the 3rd column under *Discussion of Regulation*, remove the date "March 23, 2001" and add the date "March 22, 2001". On page 15351, in the 3rd column under amendatory instruction 2, in paragraph (b), remove the date "March 23, 2001" and add the date "March 22, 2001".

Dated: March 19, 2001.

**H.M. Hamilton,**

*Commander, U.S. Coast Guard, Captain of the Port, Western Alaska, Acting.*

[FR Doc. 01-7114 Filed 3-20-01; 8:45 am]

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## DEPARTMENT OF DEFENSE

### Department of the Army, Corps of Engineers

#### 33 CFR Part 334

#### United States Marine Corps Restricted Area, New River, North Carolina, and Vicinity

**AGENCY:** U.S. Army Corps of Engineers, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Corps of Engineers is amending the regulations which established restricted areas in the waters of New River, North Carolina, and vicinity to include restricted areas for United States Marine Corps Waterborne Refueling Training Operation in the Morgan Bay Sector, Farnell Bay Sector, and Grey Point Sector. Refueling operations will occur approximately fourteen times a year. Small craft will be refueled with unleaded gasoline or diesel fuel from a tactical bulk refueling system loaded onto a floating platform or vessel. The purpose is for the Marine Corps to gain proficiency in refueling operations and associated activities in riverine environments. The restricted area previously served as a firing range; but there were not provisions for refueling operations. The changes to the regulation are necessary to safeguard Marine Corps vessels, ribbon bridges, and United States Government facilities from sabotage and other subversive acts, accidents, or other incidents of similar nature. These changes are also necessary to protect the public from potentially hazardous conditions which may exist as a result of the Marine Corps use of the area.

**EFFECTIVE DATE:** April 20, 2001.

**ADDRESSES:** U.S. Army Corps of Engineers, ATTN: CECW-OR, 441 G Street, NW., Washington, DC 20314-1000.

**FOR FURTHER INFORMATION CONTACT:** Mr. Frank Torbett, Headquarters Regulatory Branch, Washington, DC at (202) 761-4618, or Dr. G. Wayne Wright, Corps of Engineers, Wilmington District, at 910-251-4467.

**SUPPLEMENTARY INFORMATION:** Pursuant to its authorities in section 7 of the Rivers and Harbors Act of 1917 (40 Stat 266; 33 U.S.C. 1) and Chapter XIX, of the Army Appropriations Act of 1919 (40 Stat 892 U.S.C. 3) the Corps is amending the restricted area regulations in 33 CFR Part 334.440.

#### Procedural Requirements

##### a. Review Under Executive Order 12866

This rule is issued with respect to a military function of the Defense Department and the provisions of Executive Order 12866 do not apply.

##### b. Review Under the Regulatory Flexibility Act

These proposed rules have been reviewed under the Regulatory Flexibility Act (Pub. L. 96-354), which requires the preparation of a regulatory flexibility analysis for any regulation that will have a significant economic impact on a substantial number of small entities (*i.e.*, small businesses and small Governments). The Corps expects that the economic impact of the establishment of this restricted area would have practically no impact on the public, no anticipated navigational hazard or interference with existing waterway traffic and accordingly, certifies that this will have no significant economic impact on small entities.

##### c. Review Under the National Environmental Policy Act

An environmental assessment has been prepared for this action. We have concluded, based on the minor nature of the proposed additional restricted area regulations, that this action will not have a significant impact to the quality of the human environment, and preparation of an environmental impact statement is not required. The environmental assessment may be reviewed at the District Office listed at the end of **FOR FURTHER INFORMATION CONTACT**, above.

##### d. Unfunded Mandates Act

This rule does not impose an enforceable duty among the private sector and, therefore, is not a Federal private sector mandate and is not subject to the requirements of Section 202 or 205 of the Unfunded Mandates Act. We have also found under Section 203 of the Act, that small Governments

will not be significantly and uniquely affected by this rulemaking.

##### e. Submission to Congress and the GAO

Pursuant to Section 801(a) (1) (A) of the Administrative Procedure Act as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, the Army has submitted a report containing this rule to the U.S. Senate, House of Representatives, and the Comptroller General of the General Accounting Office. This rule is not a major rule within the meaning of Section 804 (2) of the Administrative Procedure Act, as amended.

#### List of Subjects in 33 CFR Part 334

Danger zones, Restricted areas, Navigation (water), Transportation, Waterways.

For the reasons set out in the preamble, the Corps amends 33 CFR Part 334, as follows:

#### PART 334—DANGER ZONE AND RESTRICTED AREA REGULATIONS

1. The authority citation for Part 334 continues to read as follows:

**Authority:** 40 Stat. 266; (33 U.S.C. 1) and 40 Stat. 892; (33 U.S.C. 3).

2. Section 334.440 is amended by adding paragraph (c)(6) to read as follows:

##### **§ 334.440 New River, NC, and vicinity; Marine Corps firing ranges.**

(c) \* \* \*

(6) No person shall enter or remain within a 2 acre area surrounding a waterborne refueling training operation, in either the Grey Point Sector, Farnell Bay Sector, or Morgan Bay Sector as described in paragraph (b) of this section, for the duration of the training operation after a notice to conduct a waterborne refueling training operation has been published in the local notice to mariners and has been broadcast over the Marine Band radio network. The 2 acre area surrounding a waterborne refueling training operation will be patrolled and persons and vessels shall clear the area under patrol upon being warned by the surface patrol craft.

\* \* \* \* \*

Dated: March 5, 2001.

**Charles M. Hess,**

*Chief, Operations Division, Directorate of Civil Works.*

[FR Doc. 01-7043 Filed 3-20-01; 8:45 am]

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