

§ 416.1018 [Amended]

■ 17. In § 416.1018, remove the words “wholly or partly unfavorable” and add in their place the words “fully or partially unfavorable”.

Subpart N—[Amended]

■ 18. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

§ 416.1441 [Amended]

■ 19. In § 416.1441, amend the third sentence of paragraph (a) by removing the words “wholly or partially favorable” and adding in their place the words “fully or partially favorable”, and amend the heading and the first sentence of paragraph (d) by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

§ 416.1443 [Amended]

■ 20. In § 416.1443, amend the fifth sentence of paragraph (a)(1), the third sentence of paragraph (b)(1), the heading and first sentence of paragraph (c)(1), the first sentence of paragraph (c)(2), and the first sentence of paragraph (c)(3) by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

§ 416.1448 [Amended]

■ 21. In § 416.1448, amend the heading of paragraph (a) by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

§ 416.1453 [Amended]

■ 22. In § 416.1453, amend the paragraph heading, the first sentence, the second sentence, and the fifth sentence of paragraph (b) by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

§ 416.1466 [Amended]

■ 23. In § 416.1466, amend the second sentence of paragraph (a) by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

§ 416.1469 [Amended]

■ 24. In § 416.1469, amend the first sentence of paragraph (b)(1) by removing the words “wholly or partially favorable” and adding in their place the words “fully or partially favorable”.

PART 418—MEDICARE SUBSIDIES**Subpart D—[Amended]**

■ 25. The authority citation for subpart D of part 418 continues to read as follows:

Authority: Secs. 702(a)(5) and 1860D–1, 1860D–14 and –15 of the Social Security Act (42 U.S.C. 902(a)(5), 1395w–101, 1395w–114, and –115).

§ 418.3680 [Amended]

■ 26. In § 418.3680, amend the second sentence by removing the words “wholly favorable” and adding in their place the words “fully favorable”.

[FR Doc. 2010–13987 Filed 6–10–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 872**

[Docket No. FDA–2008–N–0163] (formerly Docket No. 2001N–0067)

RIN 0910–AG21

Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) published a final rule in the **Federal Register** of August 4, 2009 (74 FR 38686) which classified dental amalgam as a class II device, reclassified dental mercury from class I to class II, and designated special controls for dental amalgam, mercury, and amalgam alloy. The effective date of the rule was November 2, 2009. The final rule was published with an inadvertent error in the codified section. This document corrects that error. This action is being taken to ensure the accuracy of the agency’s regulations.

DATES: This rule is effective June 11, 2010.

FOR FURTHER INFORMATION CONTACT: Michael Adjodha, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 2606, Silver Spring, MD 20993–0002, 301–796–6276.

SUPPLEMENTARY INFORMATION: Dental amalgam is a metallic restorative material that is used for the direct filling of carious lesions or structural defects in teeth. Dental amalgam is a combination of elemental mercury (liquid) and amalgam alloy (powder), which is composed primarily of silver, tin, and copper (74 FR 38686). The final rule classified the device “dental amalgam” into class II; reclassified the device “dental mercury” (hereinafter “mercury”) from class I to class II; and designated a special controls guidance document to support the class II classifications of dental amalgam, mercury, and the device “amalgam alloy.” The final rule classified all three devices together in a single regulation, by establishing a new section 21 CFR 872.3070, entitled “Dental amalgam, mercury, and amalgam alloy.”

With the establishment of a single classification regulation for the three devices, supported by a designated class II special controls guidance document, FDA also intended to remove from codification the previous classifications of dental mercury and amalgam alloy as separate devices under 21 CFR 872.3700 and 21 CFR 872.3050, respectively. FDA removed the previous classification of amalgam alloy in the codified section of the final rule (74 FR 38686 at 38714), but inadvertently did not remove the previous classification of dental mercury. This document corrects that error.

Publication of this document constitutes final action on the change under the Administrative Procedure Act (5 U.S.C. 553). This technical amendment merely removes a regulatory reference in the Code of Federal Regulations (CFR) that was inadvertently not removed in the final rule. FDA therefore, for good cause, has determined that notice and public comment are unnecessary, under 5 U.S.C. 553(b)(3)(B). Further, this rule places no burden on affected parties for which such parties would need a reasonable time to prepare for the effective date of the rule. Accordingly, FDA, for good cause, has determined this technical amendment to be exempt under 5 U.S.C. 553(d)(3) from the 30-day effective date from publication.

FDA has determined under 21 CFR 25.30(i) 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. In addition, FDA has determined that this final rule contains no collections of information. Therefore, clearance by the Office Management and

Budget under the Paperwork Reduction Act of 1995 is not required.

For the effective date of this final rule, see the **DATES** section of this document.

List of Subjects in 21 CFR Part 872

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 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

§ 872.3700 [Removed]

■ 2. Remove § 872.3700.

Dated: June 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-14083 Filed 6-10-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0371]

RIN 1625-AA00

Safety Zone; City of Martinez 4th of July Fireworks, Martinez, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the launching of fireworks being sponsored by the City of Martinez. The fireworks display will be held on July 4, 2010, on the shoreline of the Carquinez Straits. This safety zone is being established to ensure the safety of participants and spectators from the dangers associated with the pyrotechnics. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from 9 p.m. through 10:15 p.m. on July 4, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0371 and are available online by going to <http://www.regulations.gov>, selecting

the Advanced Docket Search option on the right side of the screen, inserting USCG-2010-0371 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. They are also available for inspection or copying two locations: The Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Ensign Elizabeth Ellerson, U.S. Coast Guard Sector San Francisco, at 415-399-7436 or e-mail at D11-PF-MarineEvents@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final 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), as it would be impracticable to publish an NPRM with respect to this rule because the event would occur before the rulemaking process could be completed. Because of the dangers posed by the pyrotechnics used in this fireworks display, the safety zone is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

Background and Purpose

The City of Martinez is sponsoring a brief fireworks display on July 4, 2010. The fireworks show is meant for entertainment purposes and will be used to celebrate Independence Day. The fireworks display is scheduled to launch at 9:30 p.m., on July 4, 2010, and last twenty minutes. A safety zone around the launch site is necessary to protect spectators, vessels, and other

property from the hazards associated with the pyrotechnics on the fireworks.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone on specified waters of the Carquinez Straits, for the City of Martinez Fourth of July Fireworks Display. The safety zone will apply to the navigable waters around the fireworks site within a radius of 500 feet. The fireworks launch site is on the shoreline of Martinez and will be located in position 38°01'31.77" N., 122°08'23.75" W. (NAD83).

The effect of the temporary safety zone will be to restrict general navigation in the vicinity of the fireworks launch site. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zone. This safety zone is needed to keep spectators and vessels a safe distance away from the fireworks launch site to ensure the safety of participants, spectators, and transiting vessels.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and