§ 416.1018 [Amended]

17. In § 416.1018, remove the words “wholly or partially favorable” 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:


§ 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”; 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:


§ 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”.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872


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, HHSS.

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.

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 the final rule contains no collections of information. Therefore, clearance by the Office Management and

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.

Dental mercury, designated as a class II device, is a metallic restorative material used for the direct filling of carious lesions or structural defects in teeth. Dental mercury 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 mercury” into class II; reclassified the device “dental amalgam” 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.”

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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.

**Discussion of Rule**

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