Federal Register: Dental Devices: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalga...

U.S. Food & Drug Administration

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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

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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.

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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

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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.

Sec. 872.3700 [Removed]

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2. Remove Sec. 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

SOURCE [2]

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