

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

DMB

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Certifier D. Hawkins

[Docket No. 01N-0067]

Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for the proposed rule on the classification of encapsulated amalgam alloy and dental mercury, the reclassification of dental mercury, and the issuance of special controls for amalgam alloy regulatory. The proposed rule was published in the **Federal Register** of February 20, 2002 (67 FR 7620). The agency is taking this action in response to a request for an extension. The comment period for this information closed on May 21, 2002. Elsewhere in this issue of the **Federal Register**, FDA is reopening for 60 days the comment period on the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling."

DATES: Submit written or electronic comments on the proposed rule by [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,

Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 20, 2002 (67 FR 7620), FDA published a proposed rule entitled "Dental Devices: Classification of Encapsulated Amalgam Alloy and Dental Mercury and Reclassification of Dental Mercury; Issuance of Special Controls for Amalgam Alloy."

FDA received an electronic request dated May 20, 2002, requesting that the agency extend the comment period on the proposed rule for 60 days, noting the importance of public health issues involved and explaining that there were apparently technical difficulties with the submission of electronic comments. FDA has determined that it is appropriate to grant this request.

II. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on classification, reclassification, and special controls for dental amalgam products by [*insert date 60 days after date of publication in the Federal Register*]. You must submit two copies of any comments. Individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document.

Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/5/02
July 5, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Dawn P. Hawkins