

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0064]

DMB

Display Date 7-16-02  
Publication Date 7-17-02  
Certifier J. Hawkins

**Draft Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling; Availability; Reopening of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; reopening of comment period.

---

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 60 days the comment period on the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling." Elsewhere in this issue of the **Federal Register**, the agency is announcing the extension of the comment period on a proposed rule to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices. The agency is taking this action in response to a request for an extension.

**DATES:** Submit written or electronic comments on the guidance 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:** In the **Federal Register** of February 20, 2002 (67 FR 7703), FDA published a notice announcing the availability of a draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling." In the same issue of the **Federal Register** (67 FR 7620), the agency published a proposed rule to classify encapsulated amalgam into class II, to amend the classification regulation for amalgam alloy to provide for special controls, and to reclassify dental mercury into class II. The draft guidance document is intended to serve as a special control for these devices.

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, and elsewhere in this issue of the **Federal Register** FDA is announcing the reopening of the comment period on the proposed rule. FDA believes that it is also appropriate to reopen the comment period on the guidance document.

You may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling" 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. 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]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Dawn P. Hawkins