

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 01D-0064]

DMB  
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Certifier R. LEDESMA

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

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling." This draft guidance is neither final nor is it in effect at this time. Elsewhere in this issue of the **Federal Register**, the agency is proposing 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 The draft guidance document is intended to serve as a special control for these devices.

**DATES:** Submit written or electronic comments on the draft guidance by *[insert date 90 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers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>. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

**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**

Elsewhere in this issue of the **Federal Register**, the agency is proposing 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 guidance document contains recommendations concerning the content and format of labeling for these devices.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on encapsulated amalgam, amalgam alloy, and dental mercury labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statutes and regulations. This draft guidance document is issued as a level 1 guidance consistent with the GGP regulations.

**III. Electronic Access**

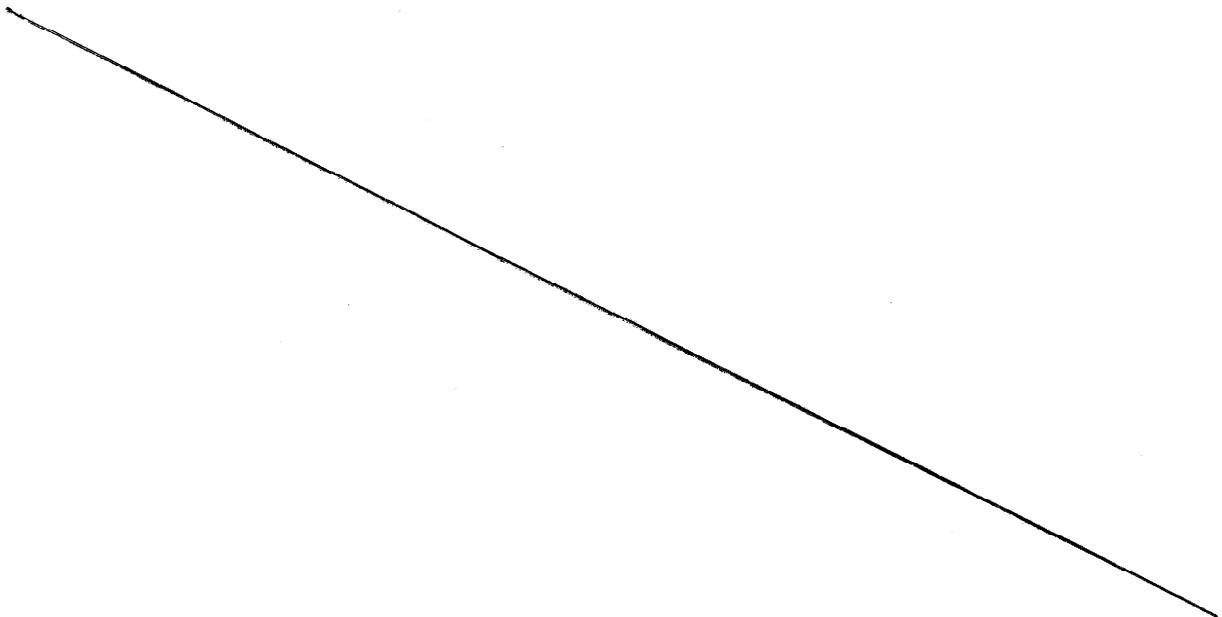
In order to receive the draft guidance entitled "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone

telephone. At the first voice prompt press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1192) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes "Special Control Guidance Document on Encapsulated Amalgam, Amalgam Alloy, and Dental Mercury Labeling," device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

#### **IV. Comments**

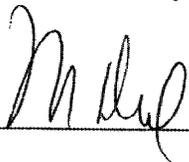
Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by [*insert date 90 days after date of publication in the **Federal Register***]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number



found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/7/2

February 7, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

4 [FR Doc. 01-<sup>2</sup>????? Filed ??-??-01<sup>2</sup>; 8:45 am]

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Regina Sedeno