

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0391]

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**Draft Guidance for Industry and FDA Staff; Class II Special Controls
Guidance Document: Dental Precious Metal Alloys and Class II Special
Controls Guidance Document: Dental Base Metal Alloys; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance documents entitled “Class II Special Controls Guidance Document: Dental Precious Metal Alloys” and “Class II Special Controls Guidance Document: Dental Base Metal Alloys.” These guidance documents describe means by which gold-based alloys and precious metal alloys for clinical use and base metal alloy devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices presently classified in class II. In the proposed rule, FDA is also proposing to exempt these devices from premarket notification.

DATES: Submit written or electronic comments on these draft guidances by [*insert date 90 days after date of publication in the Federal Register*], to ensure their adequate consideration in preparation of the final guidances. 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ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the draft guidance documents entitled “Class II Special Controls Guidance Document: Dental Precious Metal Alloys” and “Class II Special Controls Guidance Document: Dental Base Metal Alloys” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on these draft guidances to the Division of Dockets Management (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: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 123, *mea@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the draft guidance documents entitled “Class II Special Controls Guidance Document: Dental Precious Metal Alloys” and “Class II Special Controls Guidance Document: Dental Base Metal Alloys.” These guidance documents describe means by which gold-based alloys and precious metal alloys for clinical use and base metal alloy devices may comply with the requirement of class II special controls. Conformance with these guidance documents as special controls means that manufacturers

will be able to introduce their device for commercial distribution in the United States without premarket notification and clearance. If these guidance documents are made final, they will supersede “Guidance Document for the Preparation of Premarket Notifications [510(k)’s] for Dental Alloys” issued on March 3, 1997.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices presently classified in class II. If the proposed rule becomes final, manufacturers of gold-based alloys and precious metal alloys for clinical use and base metal alloy devices will need to address the issues covered in these special controls guidances in order to be exempt from the 510(k) requirements of the Federal Food, Drug, and Cosmetic Act. However, the manufacturer need only show that its device meets the recommendations of the guidances or in some way provides equivalent assurances of safety and effectiveness. These draft guidance documents are not final nor are they in effect at this time.

II. Significance of Guidance

These draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidances represent the agency’s current thinking on gold-based alloys and precious metal alloys for clinical use and base metal alloy devices. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork

Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information addressed in the guidance documents have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidances have been approved by OMB under the PRA under OMB control number 0910–0485.

IV. Comments

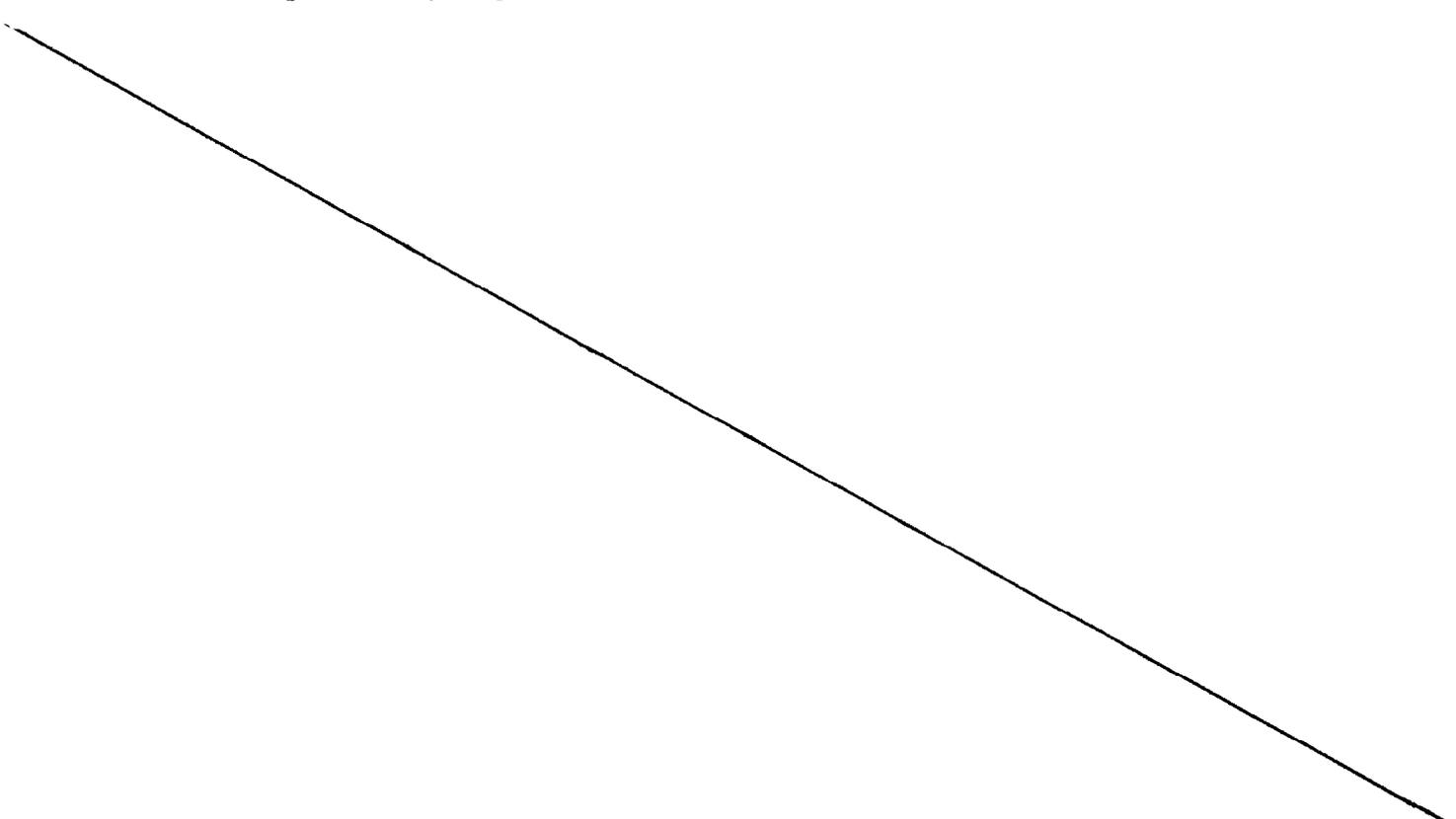
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on these draft guidances. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Copies of the draft guidance documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive “Class II Special Controls Guidance Document: Dental Precious Metal Alloys” by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1415) followed by the pound sign (#). Follow the remaining voice prompts to complete your request. To receive “Class II Special Controls Guidance Document: Dental Base Metal Alloys” by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1

to order a document. Enter the document number (1416) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of these draft guidances may also do so using the Internet. CDRH maintains a site 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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.



Dated: 10/2/03
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Linda S. Kahan

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