comment. Interested persons may submit to the Division of Dockets Management written or electronic comments by December 31, 2003. Two copies of any written 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: November 13, 2003.

Laura M. Tarantino,

Deputy Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03–29744 Filed 11–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0391]

Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Precious Metal Alloys and Class II Special Controls Guidance Document: Dental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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance documents entitled ''Class II Special Controls Guidance Document: Dental Precious Metal Alloys'' and ''Class II Special Controls Guidance Document: Dental Base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 March 1, 2004, 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: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–29740 Filed 11–28–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

OFFICE OF INVESTIGATION OFFICE OF INSPECTOR GENERAL—DHHS CASE INVESTIGATION MANAGEMENT SYSTEM FOR PRESS RELEASE FROM 10/01/2003–10/31/2003

Subject name	Address	Effective date
PROGRAM-RELATED CONVICTIONS		
ANDERSON, WALTER	TERRE HAUTE, IN	11/20/2003
ANDERSON, WALTER	LOMA LINDA, CA	11/20/2003
ANTONIAN, VICKI	FRESNO, CA	11/20/2003
BAJWA, AHSAN	FRESNO, CA	11/20/2003
BLAU, SEYMOUR	JERSEY CITY, NJ	11/20/2003
BRAVO, LAZARO	MIAMI, FL	11/20/2003
BROWN-CANTY, JOANN	CLOVER, SC	11/20/2003
CASTILLO, JOSE	HOLLISTER, CA	11/20/2003
COATES, DEBRA	FORT WORTH, TX	11/20/2003
DAVIS, TAMIKA	CHARLESTON, MS	11/20/2003
DOYLE, BRIAN	ATLANTA, GA	11/20/2003
FRENCH, MARGARET	LYNDONVILLE, NY	11/20/2003
FULTZ, CHERRY	UTICA, MS	11/20/2003
GUOZALIAN, MANOUK	LONG BEACH, CA	11/20/2003
GUPTA, RAJENDRA	OTISVILLE, NY	11/20/2003
MARTINEZ, MICHAEL	ALBUQUERQUE, NM	11/20/2003
MITCHAM, KIMBERLY	WOODVILLE, TX	11/20/2003
OSSOM, CHRISTINA	TAHLEQUAH, OK	11/20/2003
RAMOS, AMADO	THREE RIVERS, TX	11/20/2003
RODRIGUEZ, DENNIS	BRANDON, FL	11/20/2003
SAAKYAN, KARAPET	LONG BEACH, CA	11/20/2003
SAUCEDA, THOMAS	HOUSTON, TX	11/20/2003
SHEIKH, ASIF	CAMARILLO, CA	11/20/2003
SHEIKH, NAFEESA	NUTLEY, NJ	11/20/2003
STEELY, RENEE	SPRINGHILL, FL	11/20/2003
TITIZYAN, OGANES	LONG BEACH, CA	11/20/2003
VILLAMIZAR, CARLOS	ADELANTO, CA	11/20/2003