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, e-mail: *mea@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued a final rule classifying gold-based alloys and precious metal alloys for clinical use and base metal alloy devices in the **Federal Register** of August 12, 1987 (52 FR 30082). These devices were classified before the provisions of the Safe Medical Devices Act of 1990 (SMDA) broadened the definition of class II devices to establish special controls beyond performance standards. FDA published a proposed rule in the **Federal Register** of December 1, 2003 (68 FR 67097) to amend the classification regulation of these class II devices. FDA received three comments.

FDA received one comment from a consumer and one (in duplicate) from a trade association. Both comments were in support of the proposed reclassification with minor modifications suggested. The consumer comment states that the name of the regulation ''gold based alloys and precious metal alloys for clinical use'' is unscientific because gold is, by definition, a precious metal. FDA agrees with this comment and has amended § 872.3060 (21 CFR 827.3060) to read ''noble metal alloy'' and deleted ''for clinical use.''

The subject of the trade association comment was that the scope of the dental base metal alloys guidance is not clear as to what alloys are subject to the guidance. FDA agrees with this comment and has modified the scope of the guidance to define the devices not clearly addressed by the guidance.

The trade association comment also recommended that FDA's recommendation that the labeling for nickel-containing alloys contain a contraindication for hypersensitive individuals is unnecessary because nickel has been demonstrated to be biocompatible. FDA disagrees that the labeling should not contain a contraindication for nickel hypersensitive individuals. FDA believes that this warning is needed to minimize the potential for adverse events associated with improper use of this device.

Following the effective date of the final rule exempting the device, manufacturers of these devices will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. If manufacturers cannot comply with these recommendations or equivalent measures, they will not be exempt from the requirements of premarket notification and will need to submit a premarket notification and receive clearance for their device prior to marketing.

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 base metal alloy and noble 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 an 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 regarding this document. Submit a single copy of electronic comments *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 Noble 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 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 you 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 documents is available at *http://www.fda.gov/cdrh/guidances.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

Dated: August 11, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–19179 Filed 8–20–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Dates and Times: September 13, 2004, 8:30 a.m.–5:30 p.m.; September 14, 2004, 8:30 a.m.–5:30 p.m.; September 15, 2004, 8:30 a.m.–2 p.m.

Place: The Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Status: The meeting will be open to the public.

Agenda: Agenda items will include, but not be limited to: Welcome; plenary session on healthcare workforce issues as they relate to the grant programs under the purview of the Committee with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. The following topics will be addressed at the meeting: What is being done to encourage children to consider health professions careers, including what programs are in existence and what are best practices; and, what is the role of faculty development in the healthcare professions pipeline.

Proposed agenda items are subject to change as priorities dictate.

Public Comments: Public comment will be permitted at the end of the Committee meeting on September 13, 2004, and before lunch on September 14, 2004. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Jennifer Donovan, Deputy Executive Secretary, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 8–05, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–8044.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file a request in advance for a presentation, but wish to make an oral statement may register to do so at the Doubletree Hotel, Rockville, MD, on September 13, 2004. These persons will be allocated time as the Committee meeting agenda permits.

For Further Information Contact: Anyone requiring information regarding the Committee should contact Jennifer Donovan, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 8–05, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–8044.

Dated: August 17, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–19242 Filed 8–20–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given that the following committee will convene its forty-seventh meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Times: September 12, 2004, 1:30 p.m.–4:30 p.m.; September 13, 2004, 9 a.m.–4:30 p.m.; September 14, 2004, 8 a.m.–10:30 a.m.

Place: Executive Inn, 1011 N. Gloster St., Tupelo, MS 38804. Phone: 662–841–2222.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development and administration of health and human services in rural areas.

Agenda: Sunday afternoon, September 12, 2004, at 1:30 p.m., the Chairperson, the Honorable David Beasley, will open the meeting and welcome the Committee. The first session will open with a discussion of the Committee business and updates by Federal staff. This will be followed by an overview of Tupelo, MS. The Committee will then break into Subcommittee format to discuss the 2005 Report and reconvene at 4 p.m. The Sunday session will close at 4:30 p.m.

Monday morning, September 13, 2004, at 9 a.m. the Committee will break into Subcommittees and conduct site visits to local health and human services facilities. Transportation to these facilities will not be provided to the public. The Collaboration Subcommittee will visit the CREATE Foundation, the Commission on the Future of Northeast Mississippi in Tupelo, MS; the Temporary Assistance for Needy Families Subcommittee will visit Project Lift in Monroe County, MS; the Obesity Subcommittee will visit West Point in Clay County, MS; and the Obstetrics Subcommittee will visit Gilmore, MS. The Committee will reconvene at 2:00 in Tupelo, MS for a presentation by Dr. Edwin Hill, President Elect of the American Medical Association. The Committee will have an overview of the site visits and break into Subcommittees to work on the 2005 report. The Monday meeting will adjourn at 4:30 p.m.

The final session will be convened Tuesday morning, September 14, 2004, at 8:30 a.m. The Committee will summarize the Subcommittees discussions and discuss the timeline for the completion of the report. The meeting will conclude with a discussion of the letter to the Secretary. The meeting will be adjourned at 10:30 a.m.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Tom Morris, M.P.A., Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 9A–55, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Michele Pray-Gibson, Office of Rural Health Policy (ORHP), telephone (301) 443–0835. The Committee meeting agenda will be posted on ORHP's Web site *http://www.ruralhealth.hrsa.gov*.

Dated: August 16, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–19241 Filed 8–20–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Law Enforcement Training Center (FLETC)

Notice of Meeting

AGENCY: Federal Law Enforcement Training Center, Department of Homeland Security.

ACTION: Notice of meeting.

SUMMARY: The Advisory Committee to the National Center for State and Local Law Enforcement Training (National Center) at the Federal Law Enforcement Training Center will meet on September 14, 2004, beginning at 8:30 a.m.

ADDRESS: Federal Law Enforcement Training Center, 1131 Chapel Crossing Road, Glynco, GA 31524.

FOR FURTHER INFORMATION CONTACT: Reba Fischer, Designated Federal Officer, National Center for State and Local Law Enforcement Training, Federal Law Enforcement Training Center, Glynco, GA 31524, (912) 267–2343, *reba.fischer@dhs.gov.*

SUPPLEMENTARY INFORMATION: The agenda for this meeting includes remarks by the Committee Co-Chairs, Randy Beardsworth, Director of Operations, Border and Transportation Security, Department of Homeland Security, and Deborah Daniels, Assistant Attorney General, Office of Justice Programs, Department of Justice; an update on current training initiatives of the National Center; and planning of strategic goals. This meeting is open to the public. Anyone desiring to attend