

identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 7, 2002.

**John P. Burke, III,**

*Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.*

[FR Doc. 02-20521 Filed 8-13-02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 02D-0306]

#### Medical Devices; Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers." This draft guidance document was developed as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to classify these device types. This guidance is neither final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on the draft guidance by November 12, 2002.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological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.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 guidance.

#### FOR FURTHER INFORMATION CONTACT:

Mary S. Runner, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA developed this draft guidance document as a special control guidance to support the classification of certain dental sonography and jaw tracking devices into class II. FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of dental sonography and jaw tracking devices. This draft guidance document identifies the class, product code, and classification definition for these devices. In addition, it identifies the risks to health generally associated with this generic type of device, describes the device evaluation and labeling measures that FDA believes will mitigate those risks, explains how manufacturers should address those risks in a premarket notification submission, and serves as a special control that, when combined with the general controls, will address the risks associated with this generic device type.

##### II. Significance of Guidance

This draft guidance document represents the agency's current thinking on certain dental sonography and jaw tracking devices. 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 requirements of the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of

guidance documents (21 CFR 10.115). This guidance document is issued as a level 1 draft guidance in accordance with the GGP regulations.

##### III. Electronic Access

In order to receive the draft guidance entitled "Class II Special Controls Guidance Document: Dental Sonography and Jaw Tracking Devices; Draft Guidance for Industry and FDA Reviewers" via your fax machine, 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 (1393) 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. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. 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 manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at <http://www.fda.gov/cdrh>. You may search for all CDRH guidance documents at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

##### IV. Paperwork Reduction Act of 1995

This guidance contains 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 burden hours associated with 21 CFR part 807, subpart E were approved under OMB control number 0910-0120.

##### V. Comments

You may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this draft guidance by November 12, 2002. You should 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. You may see the guidance document and any

comments FDA receives in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02-20500 Filed 8-13-02; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Center on Minority Health and Health Disparities; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center on Minority and Health Disparities Special Emphasis Panel PROJECT EXPORT.

*Date:* August 7-9, 2002.

*Time:* 8:30 AM to 4:30 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* Marriott Pooks Hill, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Teresa Chapa, PHD, Chief, Division of Extramural Activities, National Center on Minority Health and Health Disparities, National Institutes of Health, Bethesda, MD 20852, 301/402-1366, [chapat@od.nih.gov](mailto:chapat@od.nih.gov)

This notice is being published less than 15 days prior to the meeting due to the time limitations imposed by the review and funding cycle.

Dated: August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-20548 Filed 8-13-02; 8:45 am]

**BILLING CODE 4140-01-M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel. Review of R01 Applications.

*Date:* August 20, 2002.

*Time:* 1 PM to 4 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* 6707 Democracy Boulevard, Building II, Room 106, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Tracy A. Shahan, PhD., Scientific Review Administrator, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Plaza, Bethesda, MD 20892, (301) 594-4952.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-20549 Filed 8-13-02; 8:45 am]

**BILLING CODE 4140-01-M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel.

*Date:* August 15, 2002.

*Time:* 4 PM to 5 PM.

*Agenda:* To review and evaluate grant applications.

*Place:* NIH, Rockledge 2, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mary Clare Walker, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5104, MSC 7852, Bethesda, MD 20892, (301) 435-1165.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

August 7, 2002.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 02-20550 Filed 8-13-02; 8:45 am]

**BILLING CODE 4140-01-M**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, August 12, 2002, 12 PM to August 12, 2002, 1 PM, NIH, Rockledge 2, Bethesda, MD, 20892 which was published in the **Federal Register** on August 5, 2002, 67 FR 50682-50683.

The meeting will be held August 13, 2002, from 11:30 AM to 12:30 PM. The location remains the same. The meeting is closed to the public.