

*Time And Date:* 8:30 a.m.–5 p.m., July 11, 2007 (Closed).

*Place:* CDC Roybal Campus, 1600 Clifton Road, Bldg. 19, Conference Room 232, Auditorium B2, Atlanta, GA 30333, Telephone (404) 639–8838.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of the “DGA International Laboratory Branch Review Panel, and the Extramural Review of Intramural Operational Research.”

*Contact Person for More Information:* Deborah Birx, Global AIDS Program, Director, CDC, Corporate Square, Bldg. 1, Room 1506, Mail Stop E–04, Atlanta, GA 30329, Telephone (404) 639–6137.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 6, 2007.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E7–11280 Filed 6–11–07; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel; Occupational Safety and Health Research, Program Announcement (PA) 07–318, and Exploratory Developmental Grants, PA PAR–06–552

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

*Time and Date:* 9 a.m.–5 p.m., July 11, 2007 (Closed).

*Place:* Marriott Waterfront, 700 Aliceanna Street, Baltimore, MD 21202.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

*Matters To Be Discussed:* The meeting will include the review, discussion, and evaluation of research grant applications in response to PA 07–318, “Occupational Safety

and Health Research,” and PAR 06–552, “Exploratory Developmental Grants.”

*Contact Person for More Information:* Stephen Olenchock, Ph.D., Scientific Review Administrator, 1095 Willowdale Road, Morgantown, WV 26506, telephone 304.285.6271.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 6, 2007.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention*

[FR Doc. E7–11288 Filed 6–11–07; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Institute for Occupational Safety and Health (NIOSH), Safety and Occupational Health Study Section (SOHSS)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

*Times and Dates:*

8 a.m.–5 p.m., June 28, 2007 (Closed).

8 a.m.–5 p.m., June 29, 2007 (Closed).

*Place:* Embassy Suites Hotel, 1900

Diagonal Road, Alexandria, Virginia 22314, telephone 703–684–5900, fax 703–684–1403.

*Purpose:* The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute’s standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute’s program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

*Matters To Be Discussed:* The meeting will convene to address matters related to the conduct of Study Section business and for the study section to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance

with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Public Law 92–463.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Price Connor, PhD, NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E–20, Atlanta, Georgia 30333, telephone 404–498–2511, fax 404–498–2571.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 5, 2007.

**Elaine L. Baker,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E7–11281 Filed 6–11–07; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D–0020]

#### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Intervertebral Body Fusion Device; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled “Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.” It was developed as a special control to support the reclassification of intervertebral body fusion devices that contain bone grafting material from class III (premarket approval) into class II (special controls). The guidance document describes a means by which these intervertebral body fusion 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 final rule to reclassify the intervertebral body fusion device that contain bone grafting material from class III into class II (special controls) and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III.

**DATES:** Submit written or electronic comments on this guidance at any time.

General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance 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>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jodi N. Anderson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3680.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of February 9, 2006 (71 FR 6778), FDA announced the availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device." Interested persons were invited to comment on the draft guidance document by May 10, 2006.

In the same **Federal Register** (71 FR 6710), FDA published a proposed rule to reclassify the intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. FDA received twelve comments on the proposed rule and draft guidance. Ten comments were on the proposed rule and are addressed in the final rule published elsewhere in this issue of the **Federal Register**. The two comments on the draft guidance suggested that FDA clarify its discussion of device sterilization and mechanical testing. FDA has updated the guidance to clarify its recommendations about these two topics.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on intervertebral body fusion 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.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1540 to identify the guidance you are requesting.

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 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>.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

**V. 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 or two paper copies of any mailed 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 31, 2007.

**Linda S. Kahan,**

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

[FR Doc. E7-11235 Filed 6-11-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

[USCG-2007-27657]

**Cooperative Research and Development Agreement: Command Center Decision Support Tools and Concept of Operations**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of intent; request for public comments.

**SUMMARY:** The Coast Guard announces its intent to enter into a Cooperative Research and Development Agreement (CRADA) with Raytheon Corporation's Mission Innovation Group, to identify and investigate, via currently available modeling and simulation techniques, the potential of conceptual Next Generation, Command Center Decision Support Tools and Concept of Operations (CONOPS) for enhancing maritime security. The Coast Guard invites public comment on the proposed CRADA and also invites other non-Federal participants, who have the interest and capability to bring similar in-kind contributions to this type of research, to be considered for entry into similar CRADAs.

**DATES:** Comments and related material on the proposed CRADA, and preliminary inquiries about participation in CRADAs, must reach the Docket Management Facility on or before July 12, 2007. Proposals from other potential, non-Federal CRADA participants must reach the Docket Management Facility on or before December 10, 2007.