

for up-to-date information on this meeting.

Agenda: On December 11, 2003, the committee will hear presentations and discuss and provide recommendations on these topics: The American Association for Blood Banks (AABB) abbreviated donor questionnaire; and blood donor deferral for exposure to Leishmaniasis. In the afternoon, the committee will hear an update on the West Nile Virus (WNV) epidemic and donor testing in 2003 including updates on WNV testing under investigational new drug applications and plans for 2004. On December 12, 2003, the committee will hear updates on these topics: The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the use of secure e-mail, a summary of the factor VIII inhibitor workshop, platelet testing and evaluation guidance, and freezing and storage temperatures for source plasma (-25 °C and -30 °C). The committee will also hear presentations and discuss and provide recommendations on the review of plasma collection nomograms.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 21, 2003. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 2 p.m. and 2:30 p.m., and 5:30 p.m. and 5:45 p.m. on December 11, 2003; and between approximately 9:30 a.m. and 10:15 a.m., and 12 noon and 12:30 p.m. on December 12, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 21, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood, or Pearline K. Muckelvene at 301-827-1281 at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-29075 Filed 11-20-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 11, 2003, from 8:30 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1184, ext. 176, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on the reclassification of the intervertebral body fusion device (cage) intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease at one or two levels from C2-C7 and L2-S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. Background information for the topic, including the agenda and questions for the committee, will be available to the public no later than 1 business day before the meeting on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: On December 11, 2003, from 9 a.m. to 6 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 2003. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On December 11, 2003, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks, Conference Management Staff, at 301-594-1283, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-29070 Filed 11-20-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; 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 Commission on Childhood Vaccines (ACCV).

Date and Time: December 3, 2003, 9 a.m.—12 noon, EST.

Place: Audio Conference Call.

The full ACCV will meet on Wednesday, December 3, from 9 a.m. to 12 noon. The meeting will be open to the public. The public can join the meeting by dialing 1-888-820-8951 on December 3 and providing the following information:

Leader's Name: Thomas E. Balbier, Jr.

Password: ACCV.

Agenda: The agenda items for December 3 will include, but are not limited to: A presentation on the Institute of Medicine's Immunization Safety Review Committee reports, "Vaccinations and Sudden Unexpected Death in Infancy" and "Influenza Vaccines and Neurological Complications"; a report of the results of the 2002 Advisory Committee Engagement Survey; and updates from the Division of Vaccine Injury Compensation, the National Department of Justice, and the National Vaccine Program Office. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857 or by e-mail at clee@hrsa.gov. 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 allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of his/her assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period on the audio conference call. These persons will be allocated time as time permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443-2124 or e-mail: clee@hrsa.gov.

Dated: November 12, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03-29067 Filed 11-20-03; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Knowledge and Opinions Regarding Organ Donation.

Date: December 8, 2003.

Time: 4 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6707 Democracy Blvd., Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Neal A. Musto, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 751, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 594-7798, muston@extra.niddk.nih.gov.

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. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 17, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-29091 Filed 11-20-03; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Neurological Disorders and Stroke Special Emphasis Panel, Neuroscience for Undergraduates.

Date: November 20, 2003.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Phillip F. Wiethorn, Scientific Review Administrator, DHHS/NIH/NINDS/DER/SRB, 6001 Executive Boulevard; MSC 9529, Neuroscience Center; Room 3203, Bethesda, MD 20892-9529, (301) 496-5388, wiethorp@ninds.nih.gov.

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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: November 17, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-29092 Filed 11-20-03; 8:45 am]

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