Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Contact: Domini Cassis, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *domini.cassis@fda.hhs.gov*, 240–276–2342.

Agenda: At the workshop, FDA will hear presentations and oral comments from interested members of the public regarding Doppler ultrasound technology as used in hand-held prenatal listening devices. FDA anticipates that presenters may include representatives from the academic, scientific, and clinical communities; device, drug, and biological product manufacturers; consumer and patient advocacy groups; and others.

Registration and Requests for Presentations: There is no fee to attend this public workshop; however, registration is required. The deadline for registration is Friday, March 10, 2006. Early registration is recommended, as seats are limited. Space will be filled in order of receipt of registration. There will be no on-site registration. Please submit registration information (including name, title, firm name, address, e-mail address, telephone number, and fax number) by March 10, 2006 (see *Contact*). Interested persons who are unable to attend the workshop are encouraged to submit written comments (see *Request for Comments*).

Those who wish to make presentations during the public workshop should submit written notification including the following: (1) The specific issue(s) you intend to address; (2) the names and addresses of all individuals that will participate in your presentation; (3) the approximate amount of time your presentation will require; and (4) two copies of all presentation materials to Domini Cassis by March 10, 2006. Presentations will be limited to the topics outlined in the **SUPPLEMENTARY INFORMATION** section of this document and, depending on the number of speakers, FDA may limit the time allotted for each presentation. If you need special accommodations due to a disability, please contact Anne Marie Williams at 301–594–1283 at least 7 days in advance of the workshop.

Request for Comments: Interested persons may submit to the Division of Dockets Management (see *Addresses*) written or electronic comments regarding this document. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Transcripts: Following the workshop, transcripts will be available for review at the Division of Dockets Management (see *Addresses*).

SUPPLEMENTARY INFORMATION:

I. Background

Since July 2002, FDA has received three citizen petitions requesting that it grant OTC status to hand-held prenatal listening devices that produce no more than 20 mW/cm2 of Doppler ultrasound intensity (FDA Docket Nos. 2002P–0338, 2003P–0438, and 2004P–0329.) Currently, these products are class II devices that are legally available only by prescription. FDA denied petitions 2002P–0338 and 2003P–0438, citing its concern over the safety of exposing a developing fetus to Doppler ultrasound without the order or instruction of a physician, and referencing the following studies:

1. ''Sinistrality—A Side-Effect of Prenatal Sonography: A Comparative Study of Young Men.'' Keiler, H., et al.; *Epidemiology*; 12:618–623 (2001).
2. ''Acceleration of Fresh Fracture Repair Using the Sonic Accelerated Fracture Healing System (SAFHS): A Review.'' Warden, S.J., et al.; *Calcified Tissue International*; 66:157–163 (2000).
3. ''Acceleration of Tibial Fracture-Healing by Non-Invasive, Low Intensity Pulsed Ultrasound.'' Heckman, J., et al.; *Journal of Bone and Joint Surgery*; 76A:26–34 (1994).
4. ''Accelerated Healing of Distal Radial Fractures With the Use of Specific, Low-Intensity Ultrasound. A Multicenter, Prospective, Randomized, Double-Blind, Placebo-Controlled Study.'' Kristiansen, T., et al.; *Journal of Bone and Joint Surgery*, 79A:961–973 (1997).
5. ''Routine Ultrasound Screening in Pregnancy and the Children's Subsequent Handedness.'' Kieler, H., et al.; *Early Human Development*; 50:233–245 (1998).

FDA reiterated its concerns in response to the most recent petition, 2004P–0329, but agreed to hold a public workshop in which relevant issues surrounding the proposal for OTC sales, distribution, and unsupervised use of these devices could be discussed. This public workshop is not intended to address legal or regulatory issues. Rather, FDA intends to collect information from outside experts and stakeholders that could help the agency better identify and evaluate the risks and benefits of uncontrolled exposure to Doppler ultrasound energy introduced through hand-held prenatal listening devices.

II. References

The above references have been placed on display in the Division of Dockets Management (see *Addresses*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7643 Filed 12–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Council for Complementary and Alternative Medicine.

Date: December 29, 2005.

Open: 12 p.m. to 1 p.m.

Agenda: The agenda includes Opening Remarks by Director, NCCAM, and a Small Business Innovative Research (SBIR) concept.

Place: 6707 Democracy Boulevard, Two Democracy, Room 401, Bethesda, Maryland 20892. (Telephone Conference Call).

Contact Person: Jane F. Kinsel, PhD., M.B.A., Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892. (301) 496–6701.

The meeting is being published less than 15 days prior to the meeting due to scheduling conflicts.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Jane Kinsel, Executive Secretary, NACCAM, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301–496–6701, Fax 301–480–9970, or via e-mail at *naccames@mail.nih.gov.*

Dated: December 16, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy, NIH.

[FR Doc. 05–24379 Filed 12–21–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Mentored Clinical Scientist (K08) Award.

Date: December 20, 2005.

Time: 10 am to 12 pm

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 38A, 8600 Rockville Pike, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Roy L. White, PhD., Division of Extramural Affairs, Review Branch, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 7202, Bethesda, MD 20892–7924. 301/435–0310. *whiterl@mail.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. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Heath, HHS).

Dated: December 14, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–24378 Filed 12–21–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Research Program Project (P01).

Date: January 12, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Irina Gordienko, PhD, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7180, MSC 7924, Bethesda, MD 20892, 301–435–0725, *gordieni@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 14, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–24381 Filed 12–21–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of 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 a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council for Biomedical Imaging and Bioengineering.

Date: January 25, 2006.

Open: 8 a.m. to 12 p.m.

Agenda: Report from the Institute Director and other Institute Staff.

Place: Bethesda North Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Closed: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Hotel and Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Anthony Demsey, Ph.D., Director, Office of Extramural Policy, National Institute of Biomedical Imaging and Bioengineering, 6701 Democracy Blvd., Room 241, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm*, where an agenda and any additional information for the meeting will be posted when available.

Dated: December 15, 2005.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–24376 Filed 12–21–05; 8:45 am]

BILLING CODE 4140–01–M