

Committee Name	Tentative Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Immunology Devices Panel	July 14, November 8.	3014512516
Medical Devices Dispute Resolution Panel	Meeting scheduled as needed.	3014510232
Microbiology Devices Panel	February 23–24, September 21–22, October 26–27.	3014512517
Molecular and Clinical Genetics Panel	April 13–14, October 5–6.	3014510231
Neurological Devices Panel	March 2–4, August 3–4, June 5–6, August 28–29, November 13–14.	3014512513
Obstetrics-Gynecology Devices Panel	March 27–28, June 5–6, August 28–29, November 13–14.	3014512524
Ophthalmic Devices Panel	March 7–8, May 18, July 13–14, September 19–20, November 2–3.	3014512396
Orthopaedic and Rehabilitation Devices Panel	February 2–3, July 27–28, October 26–27, December 11–12.	3014512521
Radiological Devices Panel	February 7, May 23, September 12, November 7.	3014512526
National Mammography Quality Assurance Advisory Committee	August 28.	3014512397
Technical Electronic Product Radiation Safety Standards Committee	October 4.	3014512399
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	March 1, May 3, July 12, September 13.	3014510564
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	March 15, October 16.	3014512548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH (NCTR)		
Science Advisory Board to NCTR	April day(s) to be announced.	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hands)	February day(s) to be announced.	3014512560

Dated: December 14, 2005.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E5–7645 Filed 12–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0329]

Hand-Held, Doppler Ultrasound Prenatal Listening Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss scientific information bearing

on whether hand-held Doppler ultrasound prenatal listening devices should be made available for use over-the-counter (OTC). This 1-day workshop is intended to provide members of the academic, scientific, and clinical communities; industry; consumer, and patient advocacy groups; and others with a forum for presenting their perspectives about available scientific literature and clinical studies relating to hand-held Doppler ultrasound prenatal listening devices. Written comments submitted to the docket before the workshop and information gathered at the workshop will be used by FDA to further identify and evaluate the risks and benefits associated with possible OTC availability of hand-held prenatal Doppler ultrasound listening devices.

Date and Time: The public workshop will be held on Wednesday, March 29, 2006, from 9 a.m. to 3:30 p.m. The deadline for registration is Friday,

March 10, 2006. Requests to make presentations at the public workshop and written or electronic comments will be accepted until Friday, March 10, 2006.

Addresses: The public workshop will be held at the Hilton Washington DC North, 620 Perry Pkwy., Gaithersburg, MD, 20877. Additional information about and directions to the facility are available on the Internet at <http://www.hilton.com/en/hi/hotels/index.jhtml?ctyhocn=GAIGHHF>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

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.

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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.