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Dated: October 20, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0038]

#### Intrapartum Electronic Fetal Monitoring With Computer Assisted Diagnosis Workshop—Exploring Methods of Evaluation

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled “Intrapartum Electronic Fetal Monitoring (EFM) With Computer Assisted Diagnosis (CAD)—Exploring Methods of Evaluation.” The objectives of this workshop are to gather ideas on how to identify and differentiate categories of EFM/CAD devices and the corresponding levels of evidence needed to validate these devices. Workshop participants will also discuss how currently available databases might be used to verify/validate intrapartum EFM/CAD algorithms.

**Date and Time:** The workshop will be held on November 10, 2008, from 8 a.m. to 5 p.m. Registrations will be accepted through October 31, 2008. Participants are encouraged to arrive early to ensure time for parking, security screening, and registration before the meeting. Security screening will begin at 7 a.m. and registration will begin at 7:30 a.m. See *Registration Information* section of this document for registration details.

**Location:** The workshop will be held at the Food & Drug Administration White Oak Campus, conference room G-2047, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FDA will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify one of the contacts listed in this document (see *Contact*) at least 7 days in advance of the workshop.

**Contact:** Sharon Andrews, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4148, FAX: 240-276-4156, [sharon.andrews@fda.hhs.gov](mailto:sharon.andrews@fda.hhs.gov); or

Elaine Blyskun, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4100, FAX: 240-276-4156, [elaine.blyskun@fda.hhs.gov](mailto:elaine.blyskun@fda.hhs.gov).

**Registration Information:** Registration may be completed online at the following Web site: <http://www.blsmmeetings.net/1368-2>. There is no registration fee for this workshop; however, all participants must submit a registration form. Space is limited, so please register as soon as possible to reserve a space. Registrations will be accepted through (see **DATES**). Persons without Internet access may contact Syreeta Tate-Jones at 301-577-0244, ext. 49 by October 31, 2008, to register.

**Agenda:** The workshop will begin with a morning session to provide a clinical and regulatory overview of intrapartum fetal monitors. Presentation topics will address fetal monitoring in general, the relationship between technology and clinical decisionmaking, the current state of EFM/CAD development, and evaluation/validation methods that may be applied to new EFM/CAD systems. In the afternoon, attendees will break into two discussion groups: (1) EFM/CAD technological development and validation and (2) the practicality of using existing databases to test new EFM/CAD algorithms. The workshop will conclude with an overview of the break-out discussions and identification of research gaps and opportunities in the field.

Dated: October 20, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Training in Primary Care Medicine and Dentistry; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

**Name:** Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD).

**Date and Time:** November 17, 2008, 8:30 a.m.–4:30 p.m. November 18, 2008, 8 a.m.–2 p.m.

**Place:** The Legacy Hotel and Meeting Centre, 1775 Rockville Pike, Rockville, Maryland 20852.

**Status:** The meeting will be open to the public.

**Purpose:** The Advisory Committee provides advice and recommendations on a broad range of issues dealing with programs and activities authorized under section 747 of the Public Health Service Act as amended by The Health Professions Education Partnership Act of 1998, Public Law 105-392. At this meeting the Advisory Committee will work on its eighth report about the re-design of the delivery of primary health care and its implications for the training of primary care practitioners. Reports are submitted to Congress and to the Secretary of the Department of Health and Human Services.

**Agenda:** The meeting on Monday, November 17, will begin with opening comments from the Chair of the Advisory Committee and introductory remarks from senior management of the Health Resources and Services Administration. The Advisory Committee will elect a new chair and two vice-chairs prior to the main agenda. In the plenary session, the Advisory Committee will discuss key elements they wish to include in the eighth report, develop an outline for the report, and draft report recommendations. The work will be done in plenary session and in small groups. On Tuesday, November 18, the Advisory Committee will continue its work on the eighth report and determine next steps in the report preparation process. The members will plan an agenda for the next Advisory Committee meeting. An opportunity will be provided for public comment.

**For Further Information Contact:** Anyone interested in obtaining a roster of members or other relevant information should write or contact Jerilyn K. Glass, M.D., PhD, Division of Medicine and Dentistry, Bureau of Health Professions, Health Resources and Services Administration, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-6822. The Web address for information on the Advisory Committee is <http://bhpr.hrsa.gov/medicine-dentistry/actpcmd>.

Dated: October 21, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

**Name:** National Advisory Council on Nurse Education and Practice (NACNEP).