

## 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.

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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

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*Registration Information:* Registration may be completed online at the following Web site: <http://www.blsm meetings.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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