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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.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.*

[FR Doc. E8-25586 Filed 10-24-08; 8:45 am]

**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.*

[FR Doc. E8-25569 Filed 10-24-08; 8:45 am]

**BILLING CODE 4165-15-P**

## 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).

*Dates and Times:* November 13, 2008, 8 a.m.–4:30 p.m. November 14, 2008, 8 a.m.–4:30 p.m.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Rockville, MD 20817.

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

*Agenda:* Agency and Bureau administrative updates will be provided.

*Purpose:* The purpose of this meeting will be to address issues relating to the nursing faculty shortage and its impact on nurse education and practice. The objectives of the meeting are: (1) To analyze achievements toward meeting recommendations that have been suggested to address the faculty shortage put forth in the National Advisory Council on Nurse Education and Practice: Second Report to the Secretary of Health and Human Services and the Congress; (2) to examine strategies instituted to address the faculty shortage; (3) to address the academic preparation of nurse educators; and (4) to address faculty salaries and any barriers to increasing faculty salaries.

During this meeting, the NACNEP council members will deliberate on the content presented and formulate recommendations to the Secretary of Health and Human Services and the Congress on the impact the faculty shortage is having on nursing education and practice. Members from professional nursing, public and private organizations will present their initiatives on addressing the nursing faculty shortage. Strategies on how to prepare nursing faculty for their role will be presented. This meeting will form the basis for NACNEP's mandated Ninth Annual Report.

*For Further Information Contact:* Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information can contact Nancy Douglas-Kersellus, Acting Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 8C-26, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-5688. Information can also be found at the following Web site: <http://bhpr.hrsa.gov/nursing/nacnep.htm>.

Dated: October 21, 2008.

**Alexandra Huttinger,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E8-25568 Filed 10-24-08; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for

licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Method of Treating and Preventing Infections in Immunocompromised Subjects With Immunostimulatory CpG Oligonucleotides

*Description of Technology:* Primary disorders of the immune system can be divided into four categories, (1) disorders of the humoral immunity, (2) disorders of cellular immunity, (3) disorders of phagocytes, and (4) disorders of complement. In addition, there are many causes of secondary immunodeficiency such as treatment with immunosuppressive or chemotherapeutic agents, protein-losing enteropathy, and infection with a human immunodeficiency virus (HIV). Generally, immunocompromised patients are unable to mount an immune response to a vaccine or an infection in the same manner as non-immunocompromised individuals.

Opportunistic infections to which individuals infected with HIV are susceptible include bacterial infections such as salmonellosis, syphilis and neurosyphilis, tuberculosis (TB), a typical mycobacterial infection, and bacillary angiomatosis (cat scratch disease), fungal infections such as aspergillosis, candidiasis (thrush, yeast infection), coccidioidomycosis, cryptococcal meningitis, and histoplasmosis, protozoal infections such as cryptosporidiosis, isosporiasis, microsporidiosis, Pneumocystis Carinii pneumonia (PCP), and toxoplasmosis, viral infections such as Cytomegalovirus (CMV), hepatitis, herpes simplex (HSV, genital herpes), herpes zoster (HZV, shingles), human papilloma virus (HPV, genital warts, cervical cancer), Molluscum Contagiosum, oral hairy leukoplakia (OHL), and progressive multifocal leukoencephalopathy (PML), and neoplasms such as Kaposi's

sarcoma, systemic non-Hodgkin's lymphoma (NHL), and primary CNS lymphoma, among others. These opportunistic infections remain principally responsible for the morbidity and mortality associated with HIV disease.

This application claims use of immunostimulatory D-type CpG oligonucleotides for the treatment of immunocompromised individuals. More specifically, the application claims use of immunostimulatory D-type CpG oligonucleotides for the treatment of individuals infected with HIV.

*Application:* Vaccine adjuvants, production of vaccines, immunotherapeutics.

*Development Status:* Preclinical studies have been performed; oligonucleotides have been synthesized.

*Inventors:* Dennis Klinman (FDA/CBER; NCI) and Daniela Verthelyi (FDA/CBER).

*Patent Status:* U.S. Provisional Application No. 60/411,944 filed 18 Sep 2002 (HHS Reference No. E-153-2002/0-US-01); U.S. Patent Application No. 10/666,022 filed 17 Sep 2003 (HHS Reference No. E-153-2002/0-US-03).

*Licensing Status:* Available for exclusive or nonexclusive licensing.

*Licensing Contact:* Peter A. Soukas, J.D.; 301-435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute, Laboratory of Experimental Immunology, Immune Modulation Group, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

#### Method of Treating Infectious and Inflammatory Lung Disease With Suppressive Oligonucleotides

*Description of Technology:* Lung disease is the number three killer in America, responsible for one in seven deaths, and lung disease and other breathing problems are the number one killer of babies younger than one year old. Today, more than thirty (30) million Americans are living with chronic inflammatory lung diseases such as emphysema and chronic bronchitis. In addition, approximately one hundred and fifty thousand (150,000) Americans are affected by acute respiratory distress syndrome (ARDS) each year.

Many lung diseases are associated with lung inflammation. For example, ARDS involves the rapid onset of