

two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.regulations.gov>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: August 26, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-20294 Filed 9-2-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 25, 2008, from 8:30 a.m. to approximately 4 p.m.

Location: Crowne Plaza Hotel, 8777 Georgia Ave., Silver Spring, MD 20910

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71),

Food and Drug Administration, 1401 Rockville Pike, Rockville, MD, 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: In open session the Committee will be briefed on the Office of Vaccine's Research and Review (OVRR), Center for Biologics Evaluation and Research (CBER) response to OVRR Office Site Visit Review Report that was presented and approved by this committee on January 25, 2007. The Committee will also hear presentations and hold discussion on the use of Madin-Darby canine kidney (MDCK) Cells for manufacture of live attenuated Influenza Virus Vaccines.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 18, 2008. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 8, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the

scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 11, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 27, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-20372 Filed 9-2-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; 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 Heritable Disorders in Newborns and Children (ACHDNC).

Dates and Times: October 1, 2008, 1 p.m. to 5 p.m.; October 2, 2008, 8 a.m. to 3 p.m.

Place: Capital Hilton, 1001 16th Street, NW., Washington, DC 20036.

Status: The meeting will be open to the public with attendance limited to space availability. Participants are asked to register for the meeting by going to the registration Web site at <http://events.SignUp4.com/ACHDNC1008>. Individuals who need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate their

needs on the registration Web site. The registration deadline is Tuesday, September 30, 2008. If there are technical problems gaining access to the Web site, please contact Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, telephone: (202) 828-5100.

Purpose: The ACHDNC was established to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The ACHDNC also provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program.

Agenda: The meeting will include presentations and continued discussions on the nomination/evaluation process for newborn screening candidate conditions. There will be presentations on emergency preparedness and contingency planning for newborn screening, as well as presentations on the continued work and reports of the ACHDNC's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training.

Proposed agenda items are subject to change as priorities dictate. The Agenda, Committee Roster and Charter, presentations, and meeting materials can be located at the home page of the Web site at <http://events.SignUp4.com/ACHDNC1008>.

Public Comments: Members of the public can present oral comments during the public comment period of the meeting. Those individuals are required to register online by Tuesday, September 30, 2008, at <http://events.SignUp4.com/ACHDNC1008>. Requests will contain the name, address, telephone number, and any professional or business affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The list of public comment participants will be posted on the Web site. Parties wishing to submit written comments should ensure that the comments are postmarked or e-mailed no later than Friday, September 26, 2008, for consideration. Comments should be submitted to Tamar R. Shealy, Meetings Manager, Conference and Meetings Management, Altarum Institute, 1200 18th Street, NW., Suite 700, Washington, DC 20036, telephone: (202) 828-5100; fax: (202) 785-3083, or e-mail: Tamar.Shealy@altarum.org.

Contact Person: Anyone interested in obtaining other relevant information should write or contact Jill F. Shuger, M.S., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443-1080, jshuger@hrsa.gov. Information on the Advisory Committee is available at <http://mchb.hrsa.gov/heritabledisorderscommittee>.

Dated: August 27, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8-20441 Filed 9-2-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Biomedical Computing and Health Informatics Study Section, October 2, 2008, 8 a.m. to October 2, 2008, 5 p.m., Hilton Washington DC/Rockville, 1750 Rockville Pike, Rockville, MD 20852, which was published in the **Federal Register** on August 18, 2008, 73 FR 48219-48220.

The meeting will be held October 2, 2008, 8 a.m. to 12:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-20192 Filed 9-2-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; 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 a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and

evaluation of individual intramural programs and projects conducted by the Clinical Center, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: September 8-9, 2008.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate the Transfusion Medicine Department Review.

Place: National Institutes of Health, Building 10, 10 Center Drive, Room 4-2551, Bethesda, MD 20892.

Contact Person: David K. Henderson, MD, Deputy Director for Clinical Care, Office of the Director, Clinical Center, National Institutes of Health, Building 10, Room 6-1480, Bethesda, MD 20892, (301) 496-3515.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the intramural research review cycle.

Dated: August 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-20190 Filed 9-2-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular, Molecular and Integrative Reproduction Study Section, September 15, 2008, 8 a.m. to September 16, 2008, 3 p.m., Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101, which was published in the **Federal Register** on August 18, 2008, 73 FR 48219-48220.

The meeting will be held one day only September 15, 2008, from 8 a.m. to 6 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: August 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-20193 Filed 9-2-08; 8:45 am]

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