CGMP requirements in 21 CFR Parts 210, 211, and 606.

In the **Federal Register** of August 6, 2001 (66 FR 40886), FDA issued a final rule that revised 21 CFR 606.151(c) to allow for the use of either a serologic crossmatch or a computer crossmatch as an acceptable method of establishing the compatibility between the donor's cell type and recipient's serum or plasma type (*i.e.,* major crossmatch). Prior to the issuance of the final rule, a blood establishment could only use a computer crossmatch if FDA gave its written approval for the use of a computer crossmatch as an alternative procedure under 21 CFR 640.120. With this revision to 21 CFR 606.151(c), establishments are no longer required to submit an application to FDA to permit use of a computer crossmatch as an alterative procedure. The guidance does not apply to those circumstances where the donor's blood has not been screened for agglutinating, coating and hemolytic antibodies. In such cases, 21 CFR 606.151(d) requires that "* * * the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate."

The guidance document describes the practices that FDA believes satisfy the requirements in 21 CFR 606.151(c) to help ensure detection of an incompatible crossmatch when using a computerized system for matching a donor's cell type with a recipient's serum or plasma type. We consider computer crossmatch an acceptable method of compatibility analysis when it is properly designed, validated, implemented, and monitored. In addition, the guidance contains recommendations for blood establishments performing compatibility testing that intend to implement a computer crossmatch procedure. For licensed establishments, the guidance also describes how to report this manufacturing change to FDA under 21 CFR 601.12.

In the **Federal Register** of June 21, 2007 (72 FR 34259), FDA announced the availability of the draft guidance entitled "Guidance for Industry: 'Computer Crossmatch' (Electronic Based Testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)" dated June 2007. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 211.68(a) and (b) and 211.100(a) have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 606.100(b), 606.121, 606.151, and 606.160 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 22, 2011,

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–10221 Filed 4–27–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0002]**

### Study Methodologies for Diagnostics in the Postmarket Setting; Public Workshop

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

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Study Methodologies for Diagnostics in the Postmarket Setting." The purpose of the public workshop is to provide a forum for discussion among FDA, governmental Agencies, academia, physicians, and various stakeholders with expertise in epidemiology, statistics, diagnostics, and biomedical research to advance the methodologies for diagnostics in the postmarket setting.

*Date and Time:* The public workshop will be held on May 12, 2011, from 8:30 a.m. to 5:15 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the workshop. Sign-in will be required.

*Location:* The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

The public workshop with also be available to be viewed via online Web-cast (see *Registration*).

*Contact Person:* Hui-Lee Wong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4611, Silver Spring, MD 20993–0002, 301–796–6234, e-mail: *hui-lee.wong@fda.hhs.gov;* or Xueying Sharon Liang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993–0002, 301–796–9601, e-mail: *XueyingSharon.Liang@fda.hhs.gov.*

*Registration:* In-person and Web-cast registration and information are available at the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/*

*ucm251696.htm.* There is no fee to attend the public workshop, but attendees must register in advance. Registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. Registration ends May 5, 2011.

If you need special accommodations because of a disability, please contact Susan Monahan at *susan.monahan@fda.hhs.gov* at least 7 days in advance of the public workshop.

**SUPPLEMENTARY INFORMATION:**

**I. Why are we holding this public workshop?**

The purpose of the public workshop is to facilitate discussion among FDA, governmental Agencies, academia, physicians, and the key stakeholders in the scientific community on issues related to the studies and methodological approaches examining diagnostics in the postmarket settings. We aim to create a dialogue between professionals with epidemiologic, statistical, and clinically relevant expertise in diagnostic devices to determine the evidence gaps and questions, datasets and approaches for conducting postmarket surveillance and robust analytic studies to improve our understanding of the performance of diagnostics at the postmarket settings.

**II. Who is the target audience for this public workshop? Who should attend this public workshop?**

This public workshop is open to all interested parties. The target audience is professionals in the scientific community with experience in epidemiology, diagnostics, or biomedical research with an interest in diagnostic devices and epidemiologic study methodology.

**III. What are the topics we intend to address at the public workshop?**

We intend to discuss a large number of methodological concerns at the workshop, including, but not limited to the following:

- Gaps and challenges in postmarket studies of diagnostics,
- Identifying and verifying emerging data sources and methodologies, and
- Fostering interdisciplinary collaboration towards identifying new opportunities in methodologies for diagnostic devices.

**IV. Where can I find out more about this public workshop?**

Background information on the public workshop, registration information, the agenda, information about lodging, transcripts, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.fda.gov/cdrh/meetings.html.*

Dated: April 22, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

[FR Doc. 2011–10273 Filed 4–27–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Initial Review Group; Interventions Committee for Adult Disorders.

*Date:* June 1, 2011.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

*Contact Person:* David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov*.

*Name of Committee:* National Institute of Mental Health Initial Review Group; Interventions Committee for Disorders Involving Children and Their Families.

*Date:* June 6, 2011.

*Time:* 8:30 a.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

*Contact Person:* David I. Sommers, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892–9606, 301–443–7861, *dsommers@mail.nih.gov*.

*Name of Committee:* National Institute of Mental Health Initial Review Group; Mental Health Services in Non-Specialty Settings.

*Date:* June 15, 2011.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC 20037.

*Contact Person:* Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, *aschulte@mail.nih.gov*.

*Name of Committee:* National Institute of Mental Health Initial Review Group; Mental Health Services in Specialty Settings.

*Date:* June 16, 2011.

*Time:* 8:30 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call)

*Contact Person:* Marina Broitman, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6153, MSC 9608, Bethesda, MD 20892–9608, 301–402–8152, *mbroitma@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: April 21, 2011.

**Anna P. Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2011–10294 Filed 4–27–11; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which