development of deoxyribonucleic acid (DNA) array methodologies, such as microarray-based comparative genomic hybridization (aCGH) and single-nucleotide polymorphism (SNP) arrays allow a high-resolution evaluation of DNA copy number alterations associated with chromosome abnormalities. Array-based cytogenetic testing is currently being implemented in the clinical setting as a method for detecting pathological genomic copy number changes.

FDA regulation and review of in vitro diagnostic devices has traditionally been a single marker-based, indication-specific process that ensures safety and effectiveness of the product. However, the results obtained from array-based cytogenetic tests are not necessarily predefined and may not be associated with known clinical syndromes. Evaluating complex devices such as array-based cytogenetic tests challenges the traditional method of FDA review.

II. Meeting Overview

During the meeting, FDA staff will present a brief background and overview of in vitro diagnostic (IVD) regulation. Specific questions related to review challenges for array-based cytogenetic tests are listed in section III of this document, Topics for Input. After the open comment session, the meeting will close with a round-table discussion between FDA staff and selected participants representing a range of constituencies. The participants in the round-table discussion will engage in a dialogue on discussion topics (see section III of this document), and provide closing thoughts. The participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives. Others in attendance at the meeting will have an opportunity to listen to the round-table discussion.

In advance of the meeting, additional information, including a meeting agenda, will be made available on the Internet. This information will be placed on file in the public docket (docket number found in brackets in the heading of this document), which is available at *http://www.regulations.gov*. This information will also be available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (select the appropriate meeting from the list).

III. Topics for Input

FDA seeks input on the following issues:

1. Clinical significance

a. The resolution of array-based cytogenetic tests and the presence of copy number variations (CNVs) in the apparently healthy population poses challenges for result interpretation. What criteria should be used to determine the clinical significance of CNVs (e.g., when categorized as benign, pathogenic, or of unknown significance)?

b. Should there be different requirements implemented for interpreting the clinical significance of deletions vs. duplications vs. translocations?

2. Result reporting and interpretation

a. Should result output be limited to results associated with known syndromes that can be adequately validated clinically and analytically?

b. What criteria (e.g., minimum overlap, size, etc.) should be used to conclude findings are indicative of known syndrome?

c. Should the performing, ordering and/or result interpretation of these tests be limited to certain professionals (e.g., clinical cytogeneticists)?

d. How does FDA ensure that the results are interpreted correctly?

3. Additional and confirmatory testing

a. Should any array-based cytogenetic testing of an affected individual include testing of parents where possible?

b. Should a second followup test (e.g., FISH) be required for result confirmation prior to reporting array-based cytogenetic results?

4. Incidental findings

Laboratories are obliged to report clinically significant findings unrelated to the test order, when identified. How can the reporting of results for diseases or conditions outside of the indications for use be restricted?

5. Clinical evaluation for approval of array-based cytogenetic devices

a. Would validation of a group of CNVs associated with well-known syndromes be acceptable as a representation of all types of detectable CNVs?

b. If yes, then which syndromes should be included and how many CNVs would be a representative number?

c. What should be used as the reference genome?

d. What studies should be performed to understand clinical specificity?

6. Use of database(s) in result reporting

a. How can the accuracy of information used in the determination of results be assured?

i. Who should develop and maintain a curated database of known/probable CNV changes and benign findings in the population?

ii. FDA regulations require that all aspects of a test involved in result output are under design controls in accordance with the Quality System regulations. When implementing the database for result reporting, how can it be assured that the database is adequately maintained and meets appropriate quality standards?

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

Dated: June 3, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–13768 Filed 6–7–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Planning Centers for Interdisciplinary Research in Benign Urology (IR–BU) (P20).

Date: July 9, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington, DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Paul A. Rushing, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Hematology Center Application Review.

Date: July 26–27, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Xiaodu Guo, MD, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4719, *guox@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Program Projects in IBD.

Date: July 26, 2010.

Time: 8 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Maria E. Davila-Bloom, PhD, Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: June 2, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13734 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

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 meeting.

The meeting 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 would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; National Cooperative Drug Discovery and Development Groups.

Date: July 16, 2010.

Time: 9 a.m. to 1 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: Vinod Charles, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6151, MSC 9606, Bethesda, MD 20892–9606, 301–443–1606, *charlesvi@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: *June 1, 2010.*

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13726 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Nursing Research Special Emphasis Panel; NINR HIV RFA Review Meeting.

Date: July 8, 2010.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Mario Rinaudo, MD, Scientific Review Administrator, Office of Review, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd (DEM 1), Suite 710, Bethesda, MD 20892, 301–594–5973, *mrinaudo@mail.nih.gov.*

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; NINR End of Life RFA Review Meeting.

Date: July 15, 2010.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd, Rm 710, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov.*

Name of Committee: National Institute of Nursing Research Special Emphasis Panel; NINR Epigenetic RFA Review Meeting.

Date: July 19, 2010.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Tamizchelvi Thyagarajan, PhD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd, Rm 710, Bethesda, MD 20892, (301) 594–0343, *tamizchelvi.thyagarajan@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program No. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: May 26, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–13712 Filed 6–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors for Basic Sciences National Cancer Institute.