

regulatory approaches, and optimal solutions to prevent, diagnose, and treat neglected tropical diseases.

The scope of this public hearing includes the issues described in sections IV.A and IV.B of this document. In addressing these issues, we ask that your comments focus particularly on preclinical studies, trial design, regulatory approaches, and optimal solutions as they relate to the prevention, diagnosis, and treatment of neglected tropical diseases. We are also providing a few examples of discussion items that would apply to each issue. However, we encourage you to comment on any subject related to the headings of sections IV.A and IV.B of this document.

#### IV. Issues for Discussion

*A. What are the challenges to developing drugs, biological products, and medical devices used to prevent, diagnose, and treat neglected tropical diseases? What are the specific areas and diseases where progress is needed?*

At a minimum, consider the following:

- Preclinical testing
- Trial design
- Regulatory approaches

*B. What can be done to advance the development of products used to prevent, diagnose, and treat neglected tropical diseases in the developing world?*

At a minimum, consider the following:

- The perceived challenges in obtaining FDA approval or clearance of a premarket submission for a product used to prevent, diagnose, or treat a neglected tropical disease
- The perceived benefit or non-benefit of:
  - orphan status designation
  - the priority review voucher program under section 524 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360n)
  - the humanitarian use device (HUD) and the humanitarian device exemption (HDE) program
  - other potential incentives
- Novel approaches to advance the development of products for neglected tropical diseases and regulatory approaches
- New strategies for international cooperation, consultation, and collaboration in the review and approval of these products
- Training or guidance necessary to support the development of products for neglected tropical diseases

#### V. Notice of Hearing Under Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15. The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner, the Economics Staff, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Office of the Chief Counsel.

Persons who wish to participate in the part 15 hearing must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). Requests to make a presentation should contain the potential presenter's name and title; address; telephone number; e-mail address; affiliation, if any; the sponsor of the presentation (e.g., the organization paying travel expenses or fees), if any; and a brief summary of the presentation, including the discussion topic(s) that will be addressed.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation.

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in § 15.30(h).

#### VI. Requests for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written notices of participation and comments for consideration at the hearing. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the hearing will remain open until October 20, 2010. You should annotate and organize your comments to identify the specific issues to which they refer (see section IV of 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 submissions 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.

#### VII. Transcripts

The hearing will be transcribed as stipulated in § 15.30(b). 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: July 14, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-17619 Filed 7-19-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Drug Abuse; 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 on Drug Abuse Special Emphasis Panel Systems Biology, HIV/AIDS, and Substance Abuse (R01).

*Date:* July 27, 2010.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Sofitel Washington DC Lafayette Square, 806 15th Street, NW., Washington, DC 20005.

*Contact Person:* Eliane Lazar-Wesley, PhD, Health Scientist Administrator, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892-8401, 301-451-4530, [elazarwe@nida.nih.gov](mailto:elazarwe@nida.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel 2010 NIDA Translational Avant-Garde Award Interviews (DP1).

*Date:* July 27, 2010.

*Time:* 8:30 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Westin Grand, 2350 M Street, NW., Washington, DC 20037.

*Contact Person:* Scott Chen, PhD, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6101 Executive Boulevard, Room 220, MSC 8401, Bethesda, MD 20892, 301-443-9511, [chensc@mail.nih.gov](mailto:chensc@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 14, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-17670 Filed 7-19-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0004]  
[FDA-225-10-0015]

#### **Memorandum of Understanding: Food and Drug Administration and the National Institutes of Health, National Institutes of Environmental Health Sciences, National Toxicology Program; and the National Institutes of Health, National Human Genome Research Institute, National Institutes of Health, Chemical Genomics Center; and the Environmental Protection Agency, Office of Research and Development**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Institutes of Health (NIH), National Institutes of Environmental Health Sciences (NIEHS), National Toxicology Program (NTP); and the NIH, National Human Genome Research Institute (NHGRI), NIH Chemical Genomics Center (NCGC); and the Environmental Protection Agency, Office of Research and Development.

This four-party Memorandum of Understanding (MOU) sets in place mechanisms to strengthen the existing collaborations that utilize the complementary expertise and capabilities of the NIEHS/NTP, the NCGC of the NHGRI, the Office of Research and Development (ORD) of the EPA, and the FDA in the research, development, validation, and translation of new and innovative test methods that characterize key steps in toxicity pathways. This MOU amends and supersedes an MOU between the first three named parties for the same purposes. A central component of this

MOU is the exploration of high throughput screening (HTS) assays and tests using phylogenetically lower animal species (e.g., fish, worms), as well as high throughput whole genome analytical methods, to evaluate mechanisms of toxicity. Ultimately, the data generated by these new tools is to be provided to risk assessors to use in the protection of human health and the environment. The goals of this MOU are to investigate the use of these new tools to: (1) Identify mechanisms of chemically induced biological activity, (2) prioritize chemicals for more extensive toxicological evaluation, and (3) develop more predictive models of in vivo biological response. Success in achieving these goals is expected to result in test methods for toxicity testing that are more scientifically and economically efficient and models for risk assessment that are more biologically based. As a consequence, a reduction or replacement of animals in regulatory testing is anticipated to occur in parallel with an increased ability to evaluate the large numbers of chemicals that currently lack adequate toxicological evaluation.

**DATES:** The agreement became effective June 4, 2010.

#### **FOR FURTHER INFORMATION CONTACT:**

David Jacobson-Kram, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Food and Drug Administration, Silver Spring, MD 20993, 301-796-0175, [david.jacobsonkram@fda.hhs.gov](mailto:david.jacobsonkram@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: July 14, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

**BILLING CODE 4160-01-S**