Dated: July 14, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0364]

Advancing the Development of Medical Products Used In the Prevention, Diagnosis, and Treatment of Neglected Tropical Diseases; Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public hearing to solicit general views and information from interested persons on issues related to advancing the development of medical products (drugs, biological products, and medical devices) used in the prevention, diagnosis, and treatment of neglected tropical diseases. In particular, FDA is seeking these views and information from interested persons on preclinical studies, trial design, regulatory approaches, and optimal solutions as they relate to the prevention, diagnosis, and treatment of neglected tropical diseases. To help solicit such views and information, FDA is seeking comments on specific issues (see section IV of this document).

DATES: *Public Hearing*: The public hearing will be held on September 22, 2010, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may extend later or end early.

Registration: Interested parties are encouraged to register early. Registration is free. Seating will be available on a first-come, first-served basis. To register, e-mail your name, title, firm name, address, and telephone numbers to *NeglectedDiseasesMtg@fda.hhs.gov* or call Ann Staten at 301–796–8504 by September 17, 2010.

Registration on the day of the public hearing will be provided on a space-available basis beginning at 7:30 a.m. To allow sufficient time for parking and clearance through security, we recommend arriving early. See section I of the **SUPPLEMENTARY INFORMATION** section for information on how to participate in the meeting. If you need special accommodations due to a disability, please contact Ann Staten (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Notice of Participation and Comments: Submit written or electronic notices of participation and comments by September 1, 2010. The administrative record of the hearing will remain open to receive additional comments until October 20, 2010.

ADDRESSES: *Public Hearing*: The public hearing will be held at 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993. You must enter through Bldg. 1 and the security check-point to reach Bldg. 31. Additional information on parking may be accessed at *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/default.htm*.

Notice of Participation and Comments: Submit notices of participation and comments, identifying the agency and Docket No. FDA–2010–N–0364, by any of the following methods:

Electronic Submissions

Submit electronic notices of participation and comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for making submissions.

Written Submissions

Submit written notices of participation and comments in the following ways:

- Fax: 301–827–6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ann M. Staten, Office of Critical Path Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg., 32, rm. 4106, Silver Spring, MD 20993–0002, 301–796–8504, *Ann.Staten@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meeting

The procedures governing the hearing are set forth in part 15 (21 CFR part 15) of FDA's regulations. If you wish to make an oral presentation during the hearing, you must submit a written notice of participation (see **ADDRESSES**) by September 1, 2010. In the written notice, submit your name, title, business affiliation, address, telephone number, and e-mail address. You should also submit a written statement for each issue in section IV of this document that you intend to address, and other pertinent information related to the topic in your presentation, the names and addresses of all individuals who plan to participate, and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Participants should submit to the docket a copy of each presentation.

We will file the hearing schedule indicating the order of presentation and the time allotted to each person to the docket. We will also e-mail or telephone the schedule to each participant before the hearing. In anticipation of the hearing presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

II. Background

Approximately one billion people worldwide suffer from neglected tropical diseases, e.g., malaria, tuberculosis, and schistosomiasis. Developing medical products to prevent, diagnose, and treat neglected tropical diseases has not met global public health needs due to an array of challenges. To encourage the development of these much needed medical products, section 740 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriation Act of 2010 (Public Law 111–80) directs FDA to establish a review group to recommend to the Commissioner of Food and Drugs (the Commissioner) appropriate preclinical studies, trial design, regulatory approaches, and optimal solutions to encourage the development of medical products to prevent, diagnose, and treat neglected tropical diseases of the developing world.

III. Purpose and Scope of the Hearing

The purpose of this public hearing is to provide advocates for patients with neglected tropical diseases, academics, health care providers, the pharmaceutical and medical device industries, and other interested parties an opportunity to address specific topics (see section IV of this document) and present to FDA their views, recommendations, and any other pertinent information related to the scope of this public hearing. This information will assist the FDA review group in making recommendations to the Commissioner regarding appropriate preclinical studies, trial design,

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]

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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.