

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Virology.

Date: May 17–18, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, saadisoh@csr.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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Viruses.

Date: May 25–26, 2010.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Soheyla Saadi, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3211, MSC 7808, Bethesda, MD 20892, 301–435–0903, saadisoh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AARA: Psychosocial Risk and Disease Prevention Competitive Revisions.

Date: May 25, 2010.

Time: 2:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard Marriott Tysons Corner, 1960–A Chain Bridge Road, McLean, VA 22102.

Contact Person: Martha M. Faraday, PhD, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3110, MSC 7808, Bethesda, MD 20892, 301–435–3575, faradym@csr.nih.gov.

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

Date: May 26–27, 2010.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Weihua Luo, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435–1170, luow@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section.

Date: May 27–28, 2010.

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

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Reed A Graves, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402–6297, gravesr@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 26, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–10139 Filed 4–29–10; 8:45 am]

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Name of Committee: Center for Scientific Review Special Emphasis Panel; ARRA: Psychosocial Risk and Disease Prevention Competitive Revisions.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA–2010–N–0218]

Considerations Regarding Food and Drug Administration Review and Regulation of Articles for the Treatment of Rare 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 regarding the Agency's regulation of drugs, biological products, and devices (e.g., therapies and diagnostics) for the treatment, diagnosis, and/or management of rare diseases. This public hearing is intended to gain from health care providers, academia, industry, patients, and other interested persons their perspectives on various aspects of the development of medical products for the diagnosis, treatment, or management of rare diseases. The input from this public hearing will help inform the work of FDA's committee for rare diseases. To help solicit such information and views, FDA is seeking responses to specific questions.

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DATES: The public hearing will be held on June 29 and 30, 2010, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early. Submit written or electronic requests for oral presentations to Paras M. Patel (see **FOR FURTHER INFORMATION CONTACT**) by May 31, 2010. Submit written comments to the Division of Dockets Management by May 31, 2010. Submit electronic comments to <http://www.regulations.gov> by May 31, 2010. Written or electronic comments will be accepted after the hearing until August 31, 2010.

ADDRESSES: The public hearing will be held at 10903 New Hampshire Ave., Bldg. 31, rm. 1503, Silver Spring, MD 20993. Additional information on parking and public transportation may be accessed at <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm058421.htm>. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Transcripts of the hearing will be available for review at the Division of Dockets Management at <http://www.regulations.gov> approximately 45 days after the hearing.

FOR FURTHER INFORMATION CONTACT: Paras M. Patel, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5271, Silver Spring, MD 20993–0002, 301–796–8660, FAX: 301–847–8621, e-mail: OPDAR@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The development of therapies and diagnostics for people with rare diseases, defined as those conditions which affect fewer than 200,000 people in the United States, presents economic and scientific challenges. Prior to the 1983 passage of (and subsequent amendments to) the Orphan Drug Act (ODA), the high development cost for therapies targeting few patients was often a prohibitive economic barrier; from 1973–1982 only 12 new drugs for rare diseases were approved by FDA. Since the ODA's passage, 357 drugs and biological products with Orphan Designation have received FDA marketing approval. More modest

advances have been made in medical devices for people with rare diseases through the humanitarian use device (HUD) and humanitarian device exemption (HDE) programs. Nevertheless for most of the estimated 7,000 rare diseases that affect an estimated 30 million Americans, no approved therapies exist.

To optimize the means by which FDA considers articles for people with rare diseases, a recent public law (Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010, Public Law 111–80, section 740) calls for the establishment of a committee of FDA employees to consider the means by which the Agency reviews the data from non-clinical studies and clinical trials, and makes decisions about marketing authorization and postmarketing surveillance for these patient populations. This committee, which was established March 11, 2010, is seeking public input to benefit from a better understanding of the opinions and suggestions of external stakeholders.

II. Purpose and Scope of the Hearing

This hearing is intended to provide advocates for patients with rare diseases, academics, health care providers, the pharmaceutical industry, and other interested parties an opportunity to relate their experience with, concerns about, and suggestions for the way FDA regulates the scientific evaluation of, marketing authorization for, and postmarket surveillance of, articles for rare diseases. The scope of such presentations may include non-clinical testing, clinical trials, and decisions regarding marketing authorization and postmarketing surveillance of products for the diagnosis or treatment of rare diseases. FDA invites public comment from interested parties on the following questions/issues:

1. Orphan drug marketing applications are reviewed under the same review process and statutory standards regarding demonstration of safety, effectiveness, and product quality as drugs for patients with non-orphan diseases or conditions. FDA is sensitive to the unique needs of patients with rare diseases as it makes approval decisions regarding the overall risk-benefit profile of therapies for the particular patient population for which they are being considered. Please comment on whether this practice has adequately addressed the needs of patients with rare diseases. If improvements are suggested, please

provide specific examples/suggestions for any recommended changes.

2. FDA designates a medical device as an HUD designed to treat or diagnose a rare disease—defined in this instance as a disease affecting or manifesting in fewer than 4,000 patients per year. Please comment on whether this practice has adequately addressed the needs of patients with rare diseases. Please also comment and provide your rationale on whether 4,000 patients constitutes an appropriate population size for an HUD determination. If improvements are suggested, please provide specific examples/suggestions for any recommended changes.

3. Current regulations for the approval of an HUD through the HDE pathway require that the application have a “description of the device and a discussion of the scientific rationale for the use of the device for the rare disease or condition” and “an explanation of why the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment” (21 CFR 814.102 and 814.104). Please comment if you believe that these standards remain appropriate for the approval of devices for rare diseases under the HDE mechanism; please also comment whether a more precise definition of probable benefit is needed.

4. Have current processes for rare disease stakeholders to communicate with FDA regarding rare disease article development been useful? How could these processes be improved? Please provide specific examples/suggestions for any recommended changes.

III. Attendance and/or Participation in the Public Hearing

The public hearing is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you wish to make an oral presentation during the hearing, you must register by submitting a written or electronic request by close of business on May 31, 2010, to Paras M. Patel (see **FOR FURTHER INFORMATION CONTACT**). You must provide your name, title, business affiliation (if applicable), address, telephone and fax numbers, e-mail address, and type of organization you represent (e.g., industry, consumer organization). You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed 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. Persons registered to make an oral presentation should check in before the hearing.

Participants should submit a copy of each presentation to Paras M. Patel. We will file the hearing schedule, indicating the order of presentation and the time allotted to each person, with the Division of Dockets Management (see **ADDRESSES**). We will mail, e-mail, or fax the schedule to each participant before the hearing. Participants are encouraged to arrive early to ensure the designated order of presentation.

If you need special accommodations due to a disability, please contact Paras M. Patel at least 14 days in advance.

IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner, the Office of Orphan Products Development, as well as representatives from the committee established by section 740 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010.

Under paragraph § 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 (§ 15.30(e)).

Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (21 CFR 10.203(a)). Under 21 CFR 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.

The hearing will be transcribed as stipulated in paragraph § 15.30(b). Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at <http://www.regulations.gov> approximately 45 days after the hearing. A transcript will also be available in either hardcopy or on a CD-ROM after submission of a Freedom of Information request. Submit written requests to the Division of Freedom of Information (HFI-35), Office of Management

Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

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

V. Request for Comments

Interested persons may submit written or electronic comments for consideration to the Division of Dockets Management (see **ADDRESSES**). Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management. You should annotate and organize your comments to identify the specific questions identified by topic to which they refer. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should 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.

Dated: April 26, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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Disease Control and Prevention's (CDC) global health strategy; (2) works in partnership to assist Ministries of Health to plan, manage effectively, and evaluate health programs; (3) achieves U.S. Government program and international organization goals to improve health, including disease eradication and elimination targets; (4) expands CDC's global health programs that focus on the leading causes of mortality, morbidity and disability, especially chronic disease and injuries; (5) generates and applies new knowledge to achieve health goals; and (6) strengthens health systems and their impact.

Office of the Director (CWA). (1) Provides strategic direction and guidance on the execution of CDC's global health strategy including decision-making, policy development and program planning and evaluation; (2) ensures the impact and effectiveness of Congressionally-mandated programs; (3) improves implementation and coordination of CDC global programs; (4) harmonizes CDC global health priorities with host country priorities to improve essential public health functions and maximize positive health outcomes, country ownership and sustainability; (5) supervises all CDC country directors and provides leadership in the selection of additional countries to expand or establish collaboration; (6) measures the performance of CDC's global health programs in terms of public health impact and fiscal accountability; (7) facilitates the conduct and maintenance of ethical and high quality, evidence-based scientific investigations by implementing regulatory requirements, monitoring human subjects compliance, and clearing scientific products; (8) promotes cross-cutting agendas and harmonizes CDC's global laboratory science activities to improve diagnostic methodologies and respond to threats of emerging pathogens; (9) provides leadership to promote growth of CDC global health programs; (10) analyzes, measures, and evaluates the global burden and distribution of disease; (11) promotes scientific innovation and best technical practices in global health surveillance, epidemiology, outbreak investigation, monitoring and evaluation, and informatics; (12) provides leadership on issues management, budget formulation and performance integration, and country-specific issues through triaging to programs; (13) participates in defining, developing, shaping and implementing U.S. global health policy and actions; (14) manages inter-governmental and

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority the Department of Health and Human Services (45 FR 67772-76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 75 FR 14608, dated March 26, 2010) is amended to reflect the reorganization of the Center for Global Health, Centers for Disease Control and Prevention.

Section C-B, Organization and Functions, is hereby amended as follows: Delete in their entirety the titles and functional statements for the Center for Global Health (CW), and insert the following:

Center for Global Health (CW). The Center for Global Health (CGH): (1) Leads the execution of the Center for