DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service (DHHS) is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA) will hold a meeting. The meeting will be open to the public.

DATES: The meeting will be held October 25, 2012 and October 26, 2012 from 9 a.m. to approximately 5 p.m. (EDT).

ADDRESSES: Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC 20005–3901.


SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995 as amended by Executive Order 13009, dated June 14, 1996. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention of HIV disease and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House Office on National AIDS Policy. The agenda for the upcoming meeting will be posted on the Council’s Web site at www.aids.gov/pacha.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact person. Pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at caroline.talev@hhs.gov. Members of the public will have the opportunity to provide comments at the meeting. Any individual who wishes to participate in the public comment session must register with Caroline Talev at caroline.talev@hhs.gov; registration for public comment will not be accepted by telephone. Public comment will be limited to two minutes per speaker. Any members of the public who wish to have printed material distributed to PACHA members at the meeting should submit, at a minimum, 1 copy of the materials to Caroline Talev, no later than close of business Thursday, October 18, 2012. Contact information for the PACHA contact person is listed above.

Dated: September 18, 2012.

B. Kaye Hayes,
Executive Director, Presidential Advisory Council on HIV/AIDS.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Notice]

Office of the Commissioner of Food and Drugs; Delegation of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

Notice is hereby given that I have delegated to the Commissioner of Food and Drugs (the Commissioner) certain authority added to the Public Health Service Act by section 801 of Public Law 110–85, the Food and Drug Administration Amendments Act of 2007 (42 U.S.C. 282(j)), pertaining to the expansion of the Clinical Trial Registry and Results Data Bank described therein. Specifically, the Commissioner is delegated the following authority:

• Section 402(j)(5)(C)(i)(I) of the Public Health Service Act (42 U.S.C. 282(j)(5)(C)(i)(I))—To determine that any clinical trial information was not submitted as required under 42 U.S.C. 282(j) or was submitted but is false or misleading in any particular and to notify the responsible party and give such party an opportunity to remedy non-compliance by submitting required revised clinical trial information not later than 30 days after such notification.

This authority may be redelegated. This delegation will be exercised in accordance with the Department of Health and Human Services’ applicable policies, procedures, guidelines, and regulations.

I ratify and affirm any actions taken by the Commissioner or her subordinates that involved the exercise of the authority delegated herein prior to the effective date of this delegation. This delegation is effective upon date of signature.

Dated: September 5, 2012.

Kathleen Sebelius,
Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Notice]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

Dated: September 5, 2012.

B. Kaye Hayes,
Executive Director, Presidential Advisory Council on HIV/AIDS.
This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Anti-Infective Drugs Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the Agency on FDA’s regulatory issues.

**Date and Time:** The meeting will be held on November 28, 2012, from 8 a.m. to 5 p.m.

**Location:** DoubleTree by Hilton Hotel Washington DC—Silver Spring, The Ballroom, 8727 Colesville Rd., Silver Spring, MD. The hotel’s phone number is 301–589–5200.

**Contact Person:** Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: AIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–874–1136 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s Web site at http://www.fda.gov/Advisory Committees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**Agenda:** The committee will discuss the safety and efficacy of new drug application (NDA) 204384, bedaquiline, tablets, submitted by Janssen Products, LP. The proposed indication for this product is for the treatment of patients with multi-drug resistant pulmonary tuberculosis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s Web site after the meeting. Background material is available at http://www.fda.gov/Advisory Committees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 13, 2012. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 2, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 5, 2012. Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diane Goyette at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at http://www.fda.gov/Advisory Committees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

**Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).**

**Dated:** September 18, 2012.

**Jill Hartzler Warner,**
Acting Associate Commissioner for Special Medical Programs.

**BILLING CODE:** 4160–01–P