

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Ei Thu Lwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-0728.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of December 20, 2019 (84 FR 70196), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry entitled “Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.” The Agency has received requests for extension of the comment period. The requests conveyed that additional time is needed to provide comments. FDA has considered the requests and is extending the comment period for 30 days, until March 19, 2020. The Agency believes that an additional 30 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

##### II. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: January 22, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Meeting of the Presidential Advisory Council on HIV/AIDS

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

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 66th full Council meeting in

Washington, DC. Agenda items will include: Discussion of *Ending the HIV Epidemic: A Plan for America* (EHE) Jurisdictional Plans, Focusing on the Four Pilot Sites: DeKalb County, Georgia; Baltimore, Maryland; East Baton Rouge, Louisiana; and the Cherokee Nation of Oklahoma; the Ready, Set, PrEP National Program; Stigma as a Barrier—Shared Experiences and Challenges from International and Domestic Perspectives; and Women and HIV. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is encouraged for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to [PACHA@hhs.gov](mailto:PACHA@hhs.gov). Pre-Registration must be complete by Monday, February 3, 2020.

**DATES:** The Council meeting is scheduled to convene on Monday, February 10, 2020 from approximately 1:00 p.m. to 7:00 p.m. ET and Tuesday, February 11, 2020 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The meeting agenda will be posted on the PACHA web page at <https://www.hiv.gov/federal-response/pacha/about-pacha>. Public attendance is limited to available space.

**ADDRESSES:** Grand Hyatt Washington, 1000 H Street NW, Washington, DC 20001.

**FOR FURTHER INFORMATION CONTACT:** Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795-7622 or [PACHA@hhs.gov](mailto:PACHA@hhs.gov). Additional information can be obtained by accessing the Council's page on the [HIV.gov](http://HIV.gov) site at [www.hiv.gov/pacha](http://www.hiv.gov/pacha).

**SUPPLEMENTARY INFORMATION:** PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection 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.

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 Caroline Talev at [PACHA@hhs.gov](mailto:PACHA@hhs.gov). Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting [PACHA@hhs.gov](mailto:PACHA@hhs.gov) by close of business Monday, February 3, 2020. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to no more than three minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at [PACHA@hhs.gov](mailto:PACHA@hhs.gov) by close of business Monday, February 3, 2020; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business Monday, February 3, 2020.

Dated: January 15, 2020.

**B. Kaye Hayes,**

*Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### National Institutes of Health

##### National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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