

number 0910–0014. The collection of information in 21 CFR part 314 for the submission of new drug applications has been approved under OMB control number 0910–0001. The submission of special protocol assessments has been approved under OMB control number 0910–0470. The submission of biologics license applications has been approved under OMB control number 0910–0338. The submission of investigational device exemptions has been approved under OMB control number 0910–0078.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at <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.*

[FR Doc. 2020–01312 Filed 1–24–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–D–4964]

#### Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products; Draft Guidance for Industry; Availability; Extension of Comment Period

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice entitled “Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products; Draft Guidance for Industry; Availability” that appeared in the **Federal Register** of December 20, 2019. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period for the notice published on December 20, 2019 (84 FR 70196). Submit either electronic or written comments on the draft guidance by March 19, 2020, to ensure that the Agency considers your comment on this

draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit either electronic or written comments as follows.

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2019–D–4964 for “Demonstrating Substantial Evidence of Effectiveness for Human Drug and Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be

made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002 or Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Stephen Ripley, Center for Biologics Evaluation and Research, Food and

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.*

[FR Doc. 2020-01322 Filed 1-24-20; 8:45 am]

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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.*

[FR Doc. 2020-01336 Filed 1-24-20; 8:45 am]

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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