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.'' The Agency will review this copy, including the claimed confidential information, in its 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, 240–402–7500.

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

Submit written requests for single copies of this guidance to the 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Scott N. Goldie, Center for Drug Evaluation and Research, Office of Biostatistics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3557, Silver Spring, MD 20993–0002, 301–796–2055, or Diane Maloney, 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products.'' The guidance provides recommendations on adjusting for covariates in the analysis of randomized clinical trials. The guidance discusses the acceptability of covariate adjustment, recommendations for implementing adjusted analyses, prespecification, selection of covariates, change from baseline analyses, statistical inference, estimands, and various statistical models. The guidance includes comments on covariate adjusting using both linear and nonlinear models.

This guidance finalizes the revised draft guidance issued on May 21, 2021 (86 FR 27627). Changes from the draft to the final guidance include changes to wording and organization and updated and clarified recommendations on computing standard errors, stratified randomization, estimands, treatment by covariate interactions, and additional methods.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Adjusting for Covariates in Randomized Clinical Trials for Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 312 pertaining to the submissions of investigational new drug applications have been approved under OMB control number 0910–0014.

III. Electronic Access

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

Dated: May 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11263 Filed 5–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0625]

Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products.'' This draft guidance is intended to help sponsors develop antidiabetic drugs for adults and children with type 1 and type 2 diabetes mellitus. In this draft guidance, antidiabetic drug refers to drugs intended to improve glycemic control, including drugs intended to reduce diabetes-related hyperglycemia (*i.e.,* antihyperglycemic drugs) and drugs intended to mitigate iatrogenic hypoglycemia associated with diabetes management.

DATES: Submit either electronic or written comments on the draft guidance by August 24, 2023 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 comments on any guidance at any time 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–2023–D–0625 for ''Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs 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, 240–402–7500.

- 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.'' The Agency will review this copy, including the claimed confidential information, in its 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, 240–402–7500.

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 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: Debra Reid, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4221, Silver Spring, MD 20993, 240–402–9143.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products.'' In this draft guidance we discuss approaches to demonstrating efficacy of antidiabetic drugs for adults and children with type 1 and type 2 diabetes mellitus. This draft guidance provides recommendations for demonstrating efficacy for drugs that are intended to reduce diabetes-related hyperglycemia (*i.e.,* antihyperglycemic drugs) and to mitigate iatrogenic hypoglycemia associated with diabetes management. The use of hemoglobin A1c as a primary endpoint for glycemic-control trials is discussed along with recommendations for trial design and conduct to allow for adequate data interpretation. The draft guidance also provides hypoglycemia definitions, trial design considerations for hypoglycemia efficacy endpoints, and hypoglycemia measurement methods. Additional efficacy endpoints are also briefly considered.

This draft guidance replaces, in part, the draft guidance for industry ''Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention'' (73 FR 11420) published in February 2008 and withdrawn in 2020. In March 2020, FDA withdrew the February 2008 draft guidance because its recommendations for safety assessment were outdated. At the same time, FDA issued the draft guidance for industry ''Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control'' March 10, 2020 (85 FR 13903) (available at *https://www.fda.gov/media/135936/download*). This draft guidance, when finalized, will provide FDA's current recommendations on this issue.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this draft guidance. The previously approved

collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: May 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–11321 Filed 5–25–23; 8:45 am]

BILLING CODE 4164–01–P

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 of a hybrid meeting.

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 convene the 77th full council meeting on Wednesday, June 28 and Thursday June 29, 2023. The meeting will convene in Phoenix, Arizona and it will also utilize virtual technologies. The meeting will be open to the public. Due to limited space, pre-registration is encouraged for members of the public who wish to attend the meeting in-person. Please email your name to *PACHA@hhs.gov* by close of business Tuesday, June 20, 2023 to pre-reigster. There will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business June 20, 2023. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business July 12, 2023. The meeting agenda will be posted on the PACHA page on HIV.gov at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will be held on Wednesday, June 28 from approximately 12 p.m.–9 p.m. (ET) and Thursday, March 29 from approximately 12 p.m.–6 p.m. (ET).

ADDRESSES: The meeting will be located at the Kimpton Hotel, Palomar Phoenix located at 2 East Jefferson Street, Phoenix, AZ 85004. To attend the meeting virtually, please visit *www.hhs.gov/live.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Senior Management Analyst, at *PACHA@hhs.gov* or *Caroline.Talev@hhs.gov.* Additional information can be obtained by accessing the Council's page on the HIV.gov site at *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 14048, dated September 30, 2021. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature. The Council consists of not more than 35 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, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and racial/ethnic and sexual and gender minority persons disproportionately affected by HIV. Council members are appointed by the Secretary.

Dated: May 17, 2023.

Caroline Talev,

Senior Management Analyst, Office of Infectious Disease and HIV/AIDS Policy, Alternate Designated Federal Official, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2023–11250 Filed 5–25–23; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Secretary; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Interagency Pain Research Coordinating Committee.

The meeting will be held as a virtual meeting and will be open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

Name of Committee: Interagency Pain Research Coordinating Committee (IPRCC).

Date: June 23, 2023.

Time: 11:00 a.m. to 12:30 p.m. Eastern Time (ET).

Agenda: The meeting will cover committee business items and IPRCC member updates. Items discussed will include updates on the Helping to End Addiction Long-Term (HEAL) Initiative and the Federal Pain Research Strategy (FPRS) research progress, and an update from the Centers for Medicare and Medicaid Services (CMS).

Deadline: Submission of intent to submit written/electronic statement for comments: Friday, June 16 by 5:00 p.m. ET.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Linda L. Porter, Ph.D., Director, Office of Pain Policy, and Planning, Office of the Director, National Institute of Neurological Disorders and Stroke, NIH, 31 Center Drive, Room 8A31, Bethesda, MD 20892.

Phone: (301) 451–4460.

Email: Linda.Porter@nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

The meeting will be open to the public via NIH Videocast *https://videocast.nih.gov/.* Visit the IPRCC website for more information: *http://iprcc.nih.gov.* Agenda and any additional information for the meeting will be posted when available.

Dated: May 22, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–11230 Filed 5–25–23; 8:45 am]

BILLING CODE 4140–01–P