

to entry for Cloud Service Providers (CSPs) with a focus on small businesses, third party assessment organizations (3PAOs), and small & large agencies, and (2) identifying and documenting ways to expedite the authorization process for Cloud Service Offerings (CSOs), such as exploring agile authorizations and other potential cost reductions, both labor and financial, with a focus on small businesses. Members of the public will have the opportunity to provide oral public comments during this meeting, and may also submit public comments in writing prior to this meeting by completing the public comment form on our website, <https://gsa.gov/fscac>. The meeting agenda will be posted on <https://gsa.gov/fscac> prior to the meeting and can be accessed by selecting the “Federal Secure Cloud Advisory Committee meetings” tab on the left, and then selecting the “October 10, 2024—Virtual” meeting accordion in order to view all meeting materials, agendas, and registration information.

#### Meeting Attendance

Both of these virtual meetings are open to the public. The meeting materials, registration information, and agendas for the meetings will be made available prior to the meetings online at <https://gsa.gov/fscac>, by selecting the “Federal Secure Cloud Advisory Committee meetings” tab on the left, and then selecting the “September 12, 2024—Virtual” meeting accordion or “October 10, 2024—Virtual” meeting accordion. Registration for attending the virtual meeting on Thursday, September 12, 2024, is highly encouraged by 5:00 p.m. EST, on Monday, September 9, 2024. Registration for attending the virtual meeting on Thursday, October 10, 2024, is highly encouraged by 5:00 p.m. EST, on Monday, October 7, 2024. After registration, individuals will receive instructions on how to attend the meeting via email.

For information on services for individuals with disabilities, or to request accommodation for a disability, please email the FSCAC staff at [FSCAC@gsa.gov](mailto:FSCAC@gsa.gov) at least 10 days prior to the meeting date. Live captioning may be provided virtually.

#### Public Comment

Members of the public attending will have the opportunity to provide oral public comment during the FSCAC meeting. Written public comments can be submitted at any time by completing the public comment form on our website, <https://gsa.gov/fscac>, located under the “Get Involved” section. All written public comments will be

provided to FSCAC members in advance of the meeting if received by Wednesday, September 4, 2024, for the Thursday, September 12, 2024 meeting; and by Wednesday, October 2, 2024, for the Thursday, October 10, 2024 meeting, respectively.

#### Margaret Dugan,

*Service-Level Liaison, Federal Acquisition Service, General Services Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Administration on Disabilities, The President’s Committee for People With Intellectual Disabilities

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The President’s Committee for People with Intellectual Disabilities (PCPID) will host a meeting for its members to discuss the 2024 PCPID Report focused on Home and Community Based Services (HCBS) and discuss emerging issues facing people with intellectual disabilities. All the PCPID meetings, in any format, are open to the public. Members of the public can join in person or virtually. This meeting will be conducted in presentation and discussion format.

**DATES:** The meeting will take place on September 26, 2024 from 9:00 a.m. to 4:00 p.m. (EST) and September 27, 2024 from 9:00 a.m. to 3:00 p.m. (EST).

Comments received by September 13, 2024 will be shared with the PCPID at the September 26–27, 2024 meeting.

#### ADDRESSES:

*Comments:* Comments and suggestions may be shared through the following [ACL.gov](https://acl.gov/form/pcpid) link: <https://acl.gov/form/pcpid>.

*In Person/Webinar/Conference Call:* The meeting is open to the public and will be hosted at the U.S. Department of Health and Human Services on September 26 and September 27, 2024. The meeting will occur at the Switzer Building Conference Room 1400 located at 330 C Street SW, Washington, DC 20201. Members of the public can observe the meeting in person or virtually. To observe the meeting in person, seating will be available for the first 25 persons to reserve seats due to space limitations. To participate in the meeting virtually, the meeting will be hosted on zoom meeting platform. In

order to observe the proceedings in person or virtually, you must register in advance of the meeting at the following link: <https://us06web.zoom.us/join/register/tZAlceGurzwjH9FLdHPW7YZKOrs3l5GuCDnq>.

**FOR FURTHER INFORMATION CONTACT:** Mr. David Jones, Director, Office of Intellectual Developmental Disabilities, 330 C Street SW, Switzer Building, Room 1126, Washington, DC 20201. Telephone: 202–795–7367. Fax: 202–795–7334. Email: [David.Jones@acl.hhs.gov](mailto:David.Jones@acl.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

*Agenda:* The Committee will discuss the 2024 PCPID Report focused on Home and Community Based Services as it relates to the areas of direct support professionals, employment, community living, and Federal support programs. And, the committee will begin to examine emerging issues faced by people with intellectual disabilities to be addressed by the Committee. This discussion will help develop a framework for the preparation of the 2025 PCPID Report to the President.

*Comments:* Stakeholder input is very important to the PCPID. Comments and suggestions especially from people with intellectual disabilities, are welcomed. If there are comments related to HCBS or other areas that you would like to inform the PCPID, please share them through the following [ACL.gov](https://acl.gov) link: <https://acl.gov/form/pcpid>.

*Background Information on the Committee:* The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The function of PCPID is to: (1) provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President and the Secretary of Health and Human Services to promote full participation of people with intellectual disabilities in their communities, such as: (A) expanding educational opportunities; (B) promoting housing opportunities; (C) expanding opportunities for competitive integrated employment; (D) improving accessible transportation options; (E) protecting rights and preventing abuse; and (F) increasing access to assistive and universally designed technologies; and (3) provide advice to the President and the Secretary of Health and Human Services to help advance racial equity and support for people with intellectual disabilities within underserved communities.

*Statutory Authority:* E.O. 14048, 85 FR 57313.

Dated: August 14, 2024.

**Jennifer Johnson,**

*Acting Commissioner, Administration on Disabilities.*

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**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2007-D-0369]

#### Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The draft guidances identified in this notice were developed using the process described in that guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by October 22, 2024 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-2007-D-0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” 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:** Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993-0002, 240-402-1062, [PSG-Questions@fda.hhs.gov](mailto:PSG-Questions@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in