

Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7381, NAV-CDER@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA's CDER is announcing a public workshop entitled, "CDER and You: Keys to Effective Engagement." This workshop is intended to help the public learn effective ways for engaging with CDER. There will be educational presentations about the drug approval process, an interactive panel featuring patient advocates who will offer engagement guidance, as well as an opportunity for questions and answers following many of the presentations. Finally, presenters will highlight innovative new procedures for requesting a meeting with CDER staff.

##### II. Participating in the Public Workshop

*Registration:* Persons interested in attending this public workshop must register online at <https://www.fda.gov/Drugs/NewsEvents/ucm592902.htm> by 6 p.m. Eastern Time, Tuesday, March 20, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting/public workshop.

If you need special accommodations due to a disability, please contact Chris Melton no later than March 26, 2018 (See **FOR FURTHER INFORMATION CONTACT.**)

*Streaming webcast of the public workshop:* This public workshop will also be available via webcast at <https://collaboration.fda.gov/cdereffectiveengagement/>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, approximately 30 days after the workshop. A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm472604.htm>.

Dated: February 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-03805 Filed 2-23-18; 8:45 am]

**BILLING CODE 4164-01-P**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2018-N-0049]

##### Promoting the Use of Complex Innovative Designs in Clinical Trials; Public Meeting; Request for Comments

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

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Promoting the Use of Complex Innovative Designs in Clinical Trials." The topic to be discussed is the use of complex innovative designs (CID) in clinical trials of drugs and biological products to inform regulatory decision making. This meeting will inform development of a guidance document as required by the 21st Century Cures Act (Cures Act) and is being conducted to meet the performance goal of convening a public workshop on CID included in the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA). This meeting will also inform the development of a CID pilot program. FDA is seeking comments on the use of CID to inform regulatory decision making and is also seeking input on the CID pilot program.

**DATES:** The public meeting will be held on March 20, 2018, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by April 20, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public meeting will be held at the FDA White Oak Campus,

10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 20, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

##### *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–2018–N–0049 for “Promoting the Use of Complex Innovative Designs in Clinical Trials; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.” 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.gpo.gov/fdsys/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.

**FOR FURTHER INFORMATION CONTACT:** Robyn Bent, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 3541, Silver Spring, MD 20993–0002, 240–402–2572, [robyn.bent@fda.hhs.gov](mailto:robyn.bent@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This public meeting is intended to support FDA guidance development as required under section 3021 of the Cures Act. Section 3021 of the Cures Act directs FDA to develop a guidance document to address several areas related to CID, including the use of complex innovative clinical trial designs, ways sponsors may obtain feedback on technical issues related to simulations, the submission of resulting information, the types of quantitative information that should be submitted for review, and recommended analysis methodologies. Before issuing the guidance, FDA is required to conduct a public meeting to gather input from the wider community of stakeholders, including academic and medical researchers, expert practitioners, drug developers, and other interested persons.

The public meeting is also intended to meet a performance goal FDA agreed to under FDARA, in accordance with the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022 letter (PDUFA VI letter), which is available at <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>. Specifically, Section J.4 of the PDUFA VI letter, “Enhancing Capacity to Review Complex Innovative Designs,” (<https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>) outlines commitments, including a public workshop to discuss various CIDs and a CID pilot program. The meeting will focus on clinical trial designs for which simulations are necessary to evaluate the operating characteristics of the trial and the acceptability of those designs in regulatory decision making.

**II. Topics for Discussion at the Public Meeting**

The purpose of this public meeting is to (1) facilitate discussion and information sharing about the use of CID in drug development and regulatory decision making and (2) obtain input from stakeholders about the CID pilot program.

The meeting will consist of four sessions. The sessions will focus on (1) complex adaptive designs; (2) other

innovative designs such as use of external/historical control subjects, Bayesian designs, and master protocols; (3) clinical trial simulations for confirmatory trial design and planning; and (4) the CID pilot program. Following each session there will be an opportunity for public comment.

After this public meeting, FDA will consider the stakeholder input from the meeting and the public docket, launch the pilot program by the end of fiscal year 2018, and publish a draft guidance within 18 months of the meeting.

Meeting updates, the agenda, and background materials (if any) will be made available at: <https://www.fda.gov/Drugs/NewsEvents/ucm587344.htm> prior to the workshop.

**III. Participating in the Public Meeting**

**Registration:** To register for the public meeting, visit <https://ComplexInnovativeDesigns.eventbrite.com> by March 13, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by March 13, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Robyn Bent (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

FDA will also hold an open public comment period at the meeting to give the public an opportunity to present their comments. Registration for open public comment will occur at the registration desk on the day of the meeting on a first-come, first-served basis.

**Streaming Webcast of the Public Meeting:** This public meeting will also be webcast. To register for the webcast of this public meeting, visit <https://ComplexInnovativeDesigns.eventbrite.com> by March 13, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. A link to the webcast will be provided following registration.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm587344.htm>.

Dated: February 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-03804 Filed 2-23-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0650]

#### Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on March 27, 2018, from 8 a.m. to 5 p.m.

**ADDRESSES:** Tommy Douglas Conference Center, the Ballroom, 10000 New Hampshire Ave., Silver Spring, MD 20903. The conference center's telephone number is 240-645-4000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Information about the Tommy Douglas Conference Center can be accessed at: <https://www.tommydouglascenter.com/>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-0650. The docket will close on March 23, 2018. Submit either electronic or written comments on this public meeting by March 23, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 23, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 23, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before March 13, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit 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").

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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-2018-N-0650 for

"Psychopharmacologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." FDA 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.gpo.gov/fdsys/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