

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 mail 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:

Regarding the guidance: Stephen Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1446, Silver Spring, MD 20993–0002, 301–796–1418, or 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.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, regulatory authorities and industry associations from around the world have participated in many important initiatives to promote international harmonization of regulatory requirements under the ICH. FDA has participated in several ICH meetings designed to enhance harmonization and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the FDA; the Japanese

Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidances.

In the **Federal Register** of February 21, 2017 (82 FR 11225), FDA published a notice announcing the availability of a draft guidance entitled “Q11 Development and Manufacture of Drug Substances—Questions and Answers (Regarding the Selection and Justification of Starting Materials).” The notice gave interested persons an opportunity to submit comments by March 23, 2017.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in August 2017.

The guidance consists of questions and answers that were developed to clarify the principles for selecting starting materials described in the ICH guidance “Q11 Development and Manufacture of Drug Substances,” published November 20, 2012 (77 FR 69634). The guidance provides guidance on selecting and justifying starting materials, in particular for the synthesis of chemical entity drug substances.

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 “Q11 Development and Manufacture of Drug Substances—Questions and Answers (Chemical Entities and Biotechnological/Biological Entities).” 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at <https://www.regulations.gov>, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: February 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Center for Drug Evaluation and Research and You: Keys to Effective Engagement; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) is announcing the following public workshop entitled “CDER and You: Keys to Effective Engagement.” The purpose of the public workshop is to build upon previous efforts to help advocates understand how they can engage with FDA to enhance drug development and safety. This marks the third annual CDER public workshop for patient advocacy groups.

DATES: The public workshop will be held on April 3, 2018, from 8 a.m. to 3 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20903. Entrance for the public workshop 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>.

FOR FURTHER INFORMATION CONTACT: Chris Melton, Center for Drug Evaluation and Research, Food and

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. To get a quick overview of the Connect Pro program, visit 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.

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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.