4164-01-P

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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