4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Navigating the Center for Drug Evaluation and Research: What You Should Know for 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 sponsoring a public workshop entitled "Navigating CDER: What You Should Know for Effective Engagement." The purpose of this public workshop is to help the public and patient advocacy groups gain a better understanding of how to effectively engage CDER.

DATES: The public workshop will be held on March 31, 2016, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak campus, 10903 New Hampshire Ave., Building 31 (The Great Room A, B, and C), Silver Spring, MD 20993. 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 http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

FOR FURTHER INFORMATION CONTACT: Shawn Brooks, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-6509, email: NAV-CDER@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop entitled "Navigating CDER: What You Should Know for Effective Engagement." This public workshop is intended to enhance the public and advocacy groups' ability to effectively engage FDA's CDER. The presentations are intended to provide information on how best to interact with CDER. There will be an opportunity for questions and answers following each presentation.

Registration: There is no registration fee to attend the public workshop. Early registration is recommended because seating is limited, and registration will be on a first-come, first-served basis. There will be no onsite registration. Persons interested in attending this workshop must register online at http://www.fda.gov/Drugs/NewsEvents/ucm472604.htm before March 24, 2016. For those without Internet access, please contact Shawn Brooks (see FOR FURTHER INFORMATION CONTACT) to register.

If you need special accommodations due to a disability, please contact Shawn Brooks (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: A transcript of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at http://www.regulations.gov approximately 30 days after the workshop. Transcripts will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at http://www.fda.gov.

Dated: January 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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