This document is scheduled to be published in the
Federal Register on 03/31/2017 and available online at
https://federalregister.gov/d/2017-06370, and on **FDsys.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Roadmap for Engaging with the Food and Drug Administration's Center for Drug Evaluation and Research; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research (CDER), is announcing the following public workshop entitled "Roadmap for Engaging with FDA's Center for Drug Evaluation and Research (CDER)." The purpose of this workshop is to help the public learn how to successfully engage with CDER.

DATES: The public workshop will be held on May 12, 2017, from 9 a.m. to 3 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20903-0002. 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 is announcing a public workshop entitled "Roadmap for Engaging with FDA's Center for Drug Evaluation and Research (CDER)." This workshop is intended to help the public learn the most effective ways to successfully engage with CDER. There will be presentations on learning about the drug approval process, as well as the opportunity for questions and answers following each presentation.

II. Participating in the Public Workshop

Registration: Persons interested in attending this workshop must register online at https://www.eventbrite.com/e/fda-public-workshop-roadmap-for-engaging-with-fdas-center-for-drug-evaluation-and-research-cder-tickets-28608664285?utm_source=eb_email&utm_medium=email&utm_campaign=new_event_email&utm_term=viewmyevent_button. 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. Persons interested in attending this public workshop must register by May 5, 2016, 6 p.m. EST. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. 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 workshop.

If you need special accommodations due to a disability, please contact Chris Melton no later than May 1, 2017.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be assessable at https://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy 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 https://www.fda.gov.

Dated: March 27, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-06370 Filed: 3/30/2017 8:45 am; Publication Date: 3/31/2017]