

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 meeting must register by midnight Eastern Time on September 25, 2017. 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 you need special accommodations due to a disability, please contact Juanita Yates (see **FOR FURTHER INFORMATION CONTACT**) no later than September 18, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation. All requests to make oral presentations must be received by September 18, 2017. We will determine the amount of time allotted to each presenter and will select and notify participants by September 25, 2017.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please visit the following Web site to register: <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/default.htm>.

FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites 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/Food/DietarySupplements/default.htm>.

Dated: August 28, 2017.

Anna K. Abram,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration, Center for Drug Evaluation and Research Rare Diseases Public Workshop: Strategies, Tools, and Best Practices for Effective Advocacy in Rare Diseases Drug Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is sponsoring a public workshop entitled “CDER Rare Diseases Public Workshop: Strategies, Tools, and Best Practices for Effective Advocacy in Rare Diseases Drug Development.” This public workshop builds upon previous CDER patient advocacy public workshops and is primarily for the rare disease community to help them effectively understand what FDA needs to enhance drug development. This effort is consistent with FDA’s efforts to support the integration of patient experience in drug development programs, including through implementation of the “Patient-Focused Drug Development” provisions of the 21st Century Cures Act (Cures Act). This public workshop will include case studies demonstrating the beneficial overlap of effective advocacy techniques and FDA regulations in rare disease drug development.

DATES: The public workshop will be held on October 30, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 (the Great Room), 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 <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Francis Kalush, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-5429, PASE-RARE-DISEASES@fda.hhs.gov

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop entitled

“CDER Rare Diseases Public Workshop: Strategies, Tools, and Best Practices for Effective Advocacy in Rare Diseases Drug Development.” The purpose of the public workshop, consistent with FDA’s broad effort to more comprehensively include patients’ perspectives and experiences with a disease or condition in the drug development process, including through implementation of the “Patient-Focused Drug Development” provisions of the Cures Act, is to aid in bridging the gap between rare disease patients’ stories and data needed to support drug development. This public workshop will include presentations on strategies, tools, and best practices on key aspects of rare diseases drug development and engaging with FDA. 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 public workshop must register online at <https://www.fda.gov/Drugs/NewsEvents/ucm565398.htm> before September 30, 2017. For those without internet access, please contact Francis Kalush (see **FOR FURTHER INFORMATION CONTACT**) to register.

If you need special accommodations due to a disability, please contact Francis Kalush (see **FOR FURTHER INFORMATION CONTACT**) no later than October 23, 2017.

Transcripts: A transcript of the public workshop will be available for review at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and on the internet at <https://www.regulations.gov> approximately 30 days after the public 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 <https://www.fda.gov>.

Dated: August 30, 2017.

Anna K. Abram,

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

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