4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration Small Business and Industry Assistance Regulatory Education for Industry Spring Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER), together with the Center for Devices and Radiological Health (CDRH), is sponsoring a 2-day public conference entitled "FDA Small Business and Industry Assistance Regulatory Education for Industry (REdI) Spring Conference." The goal of this public conference is to provide direct, relevant, and helpful information on the key aspects of drug and medical device regulations in order to increase regulatory certainty and predictability for pharmaceutical and/or medical device industry. Our primary audience is that of small manufacturers of drug and/or medical devices who want to learn about how FDA approaches the regulation of drugs and medical devices and for whom increased certainty and predictability will help to decrease the regulatory burdens that can be associated with a lack of understanding of, or familiarity with, FDA's drug and medical device regulations. However, anyone involved in the pharmaceutical and/or medical device industry may attend.

DATES: The public conference will be held May 9 and 10, 2017, from 8:30 a.m. to 4:30 p.m. See the SUPPLEMENTARY INFORMATION section for registration information.

ADDRESSES: The public conference will be held in the High Ballroom, located on the Lobby Level of the Renaissance Atlanta Midtown Hotel, 866 W. Peachtree St., NW, Atlanta, GA 30308. The hotel's phone number is 678-412-2400.

FOR FURTHER INFORMATION CONTACT: Brenda Stodart, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6707, email: cdersbia@fda.hhs.gov; or Elias Mallis, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-7100, email: DICE@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled "FDA Small Business and Industry Assistance Regulatory Education for Industry Spring Conference." This public conference is intended to increase the drug and medical device industry's awareness of applicable FDA regulations. There will be an opportunity for questions and answers following each presentation.

II. Topics for Discussion at the Conference

This 2-day, FDA-led forum offers the opportunity to interact with FDA subject matter experts from across CDER and CDRH. The following information will be discussed:

- CDER Investigational New Drug Application (IND) Review Process: Types of IND; Content and Format of an IND; Chemistry Manufacturing and Controls; Pharmacology/Toxicology; Drug Inspections
- CDRH: 510(k); Biocompatibility in Premarket Submissions; Non-Conforming Product; Device Inspections

III. Participating in the Public Conference

Registration: There is no fee to attend the public conference. Space is limited, and registration will be on a first-come, first-served basis. To register, please complete registration online at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm545309.htm. Early registration is recommended. Registrants will receive email confirmation when they have been accepted, and reminder emails will be sent to registrants 2 days before the conference. If time and space permit, onsite registration will be available beginning at 7:30 a.m. on each day of the public conference. If you need special accommodations due to disability, please contact info@sbiaevents.com at least 7 days in advance.

Streaming Webcast of the Public Conference: This public conference will also be Webcast. Persons interested in viewing the Webcast must register to receive a confirmation email with the Webcast link.

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 Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

Transcripts: Transcripts will not be available.

Dated: April 19, 2017.

Anna K. Abram,

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

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