4164-01-P

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 Small Business and Industry Assistance Regulatory Education for Industry Generic Drugs Forum; 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) is sponsoring a 2-day public conference entitled "FDA CDER Small Business and Industry Assistance (SBIA) Regulatory Education for Industry (REdI) Generic Drugs Forum." The goal of this public conference is to provide direct, relevant, and helpful information on the key aspects of the generic drug development process. Our primary audience is that of small manufacturers within the generic drug industry. However, anyone involved in the pharmaceutical industry may attend.

DATES: The public conference will be held April 4-5, 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 Pinnacle Ballroom located on the 2nd floor of DoubleTree by Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD 20910.

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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public conference entitled "FDA CDER Small Business and Industry Assistance Regulatory Education for Industry Generic Drugs Forum." This public conference is intended to increase the generic drug industry's awareness of applicable FDA regulations.

II. Topics for Discussion at the Public Conference

This 2-day, FDA-led forum offers the opportunity to interact with FDA subject matter experts from across CDER involved in the Generic Drug Review Program. It will provide up-to-date information on program progress and current initiatives and present a high-level regulatory overview of the complete ANDA review pathway.

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/ucm540969.htm?utm_source=FRN&utm_campaign=GDF2017. 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: March 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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