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.

ADDRESS: 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, 301–796–7607, 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@sbievents.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.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–05602 Filed 3–21–17; 8:45 am]
BILLING CODE 4164–01–P
ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0955–0009 which expires on May 31, 2017. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before May 22, 2017.

ADDRESSES: Submit your comments to Information.Collection.Clearance@hhs.gov or by calling (202) 690–5683.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0955–0009–60D for reference.

Information Collection Request Title: Customer Relationship Management (CRM) Tool.

OMB No.: 0955–0009.

Abstract: The Customer Relationship Management (CRM) application is a nimble business intelligence tool being used by more than 1,500 users at ONC partner organizations and grantees. The CRM collects data from a large number of users throughout the United States who are “on the ground” helping healthcare providers adopt and optimize their IT systems, it provides near real-time data about the adoption, utilization, and meaningful use of EHR technology. Approximately half of all Primary Care Providers in the nation are represented in the CRM tool; data points include provider location, credential, specialty, whether live on an EHR and what system, whether they’ve reached MU, the time between these, and narrative barriers experienced by many of these.

For Further Information Contact: Gustavo Seinos, MPH, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.6, Washington, DC 20201. Please direct all inquiries to cfsac@hhs.gov.

Supplementary Information: The CFSAC is authorized under 42 U.S.C.217a, Section 222 of the Public Health Service Act, as amended. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health (ASH), on issues related to myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The issues can include factors affecting access and care for persons with ME/CFS; the science and definition of ME/CFS; and broader public health, clinical, research, and educational issues related to ME/CFS.

The agenda for this meeting, call-in information and location will be posted on the CFSAC Web site http://www.hhs.gov/ash/advisory-committees/cfscan/meetings/index.html.

A half hour of public comment via telephone will be scheduled for the first half day of the webinar and an entire hour for the second day of the webinar. Individuals will have five minutes to present their comments. Priority will be given to individuals who have not provided public comment within the previous year. We are unable to place international calls for public comments. To request a time slot for public comment, please send an email to cfsac@hhs.gov by June 1, 2017. The email should contain the speaker’s