4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Medical Devices--The Case for Quality

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Office, in cosponsorship with the FDA Medical Device Industry Coalition, Inc. (FMDIC), is announcing a public workshop entitled "Medical Devices--the Case for Quality." The public workshop is intended to seek input from representatives of medical device manufacturers and other stakeholders on best practices, what has worked for them, and what FDA can do to inspire quality efforts. This event will also focus on various topics of interest for those industry representatives who are responsible to ensure compliance with FDA regulations.

Date and Time: The meeting will be held on April 11, 2014 from 8 a.m. to 5 p.m.

Location: The meeting will be held at Wyndham Dallas Suites-Park Central, 7800 Alpha Rd., Dallas, TX 75240. Directions and lodging information are available at the FMDIC, Inc. Web site at http:/www.fmdic.org/.

Contact: C. Sue Thomason, Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204, 214-253-5203, FAX: 214-253-5318, email: sue.thomason@fda.hhs.gov.

Registration: FMDIC has early registration (industry $250, government with ID $150, student $50) available until March 11, 2014. Registration after March 11, 2014, increases to

industry $300, government with ID $200, with student registration staying the same at $50. To register online, please visit http://www.fmdic.org/. As an alternative, send registration information including the registrant's name, title, organization, address, telephone and fax numbers, and email address (for each registrant), along with a check or money order (covering all registration fees) payable to FMDIC, Inc., to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205.

FMDIC, Inc. accepts registrations onsite on the day of the event beginning at 7:30 a.m. at the regular registration fee stated above. Registration onsite will be accepted on a space-available basis on the day of the public workshop beginning at 7:30 a.m. Please note that due to popularity, similar past events have reached maximum capacity well before the day of the event. The cost of registration at the site is $300 payable to FMDIC, Inc. The registration fee will be used to offset expenses of hosting the event, including continental breakfast, lunch, audiovisual equipment, venue, materials, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact C. Sue Thomason (see Contact) at least 7 days in advance.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop.

SUPPLEMENTARY INFORMATION:

The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This

workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the public workshop is to present information that will enable manufacturers and regulated industry to better comply with FDA's medical device requirements. Please visit the www.fmdic.org Web site for the agenda and for information about the presenters at the workshop.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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