4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Region (SWR), Dallas District Office (DALDO), in collaboration with the FDA Medical Device Industry Coalition (FMDIC), is announcing a public workshop entitled "Educational Forum on Medical Device Reporting, Complaint Files, and Recalls, Corrections, and Removals." The purpose of the public workshop is to provide information about FDA's Medical Device Quality Systems Regulation (QSR) to the regulated industry, particularly small businesses.

Date and Time: The public workshop will be held on June 15, 2012, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Renaissance Dallas Hotel, 2222 Stemmons Freeway, Dallas, TX, 75207. Directions and lodging information are available at the FMDIC Web site at http://www.fmdic.org/.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, email david.arvelo@fda.hhs.gov.

Registration: FMDIC has a $250 early registration fee. Discounts for full-time students and government employees with valid identification are available. Early registration ends June 1, 2012. Registration is $300 thereafter. For more information on fees and/or to register online, please visit http://www.fmdic.org/. As an alternative, you may send registration information including name, title, firm name, address, telephone and fax numbers, and e-mail, along with a check or money order for the appropriate amount payable to the FMDIC, to FMDIC Registrar, 4447 N. Central Expressway, suite 110 PMB197, Dallas, TX 75205. Registration on site 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 the FMDIC. The registration fee will be used to offset expenses of hosting the event including continental breakfast, lunch, refreshments, venue, materials, audiovisual equipment, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact David Arvelo (see Contact Person) at least 21 days in advance.

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 (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 is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device QSR. The following topics will be discussed at the workshop: (1) The role of complaint files, (2) medical device reporting, (3) medical device recalls, corrections, and removals, and (4) Corrective and Preventive Actions as They Relate to Complaints.

Transcripts: Transcripts of this event will not be available due to the format of this workshop. Handouts will be posted online at http://www.fmdic.org/ or may be requested in writing from David Arvelo (see Contact Person), after the public workshop.

Dated: May 1, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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