DATES). For additional information about the purpose of the meeting, topics for discussion, and registration see the September 23, 2013, **Federal Register** notice.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03587 Filed 2–18–14; 8:45 am]

BILLING CODE 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.

[FR Doc. 2014–03584 Filed 2–18–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0157]

Study Approaches and Methods To Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting; Public Meeting, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Study Approaches and Methods to Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting.'' The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, public health agencies, health care providers, and the general public concerning challenges in designing and implementing pregnancy registries and other methods of evaluating the post-approval safety profile of drugs and biological products in pregnant women. The input from this meeting and public docket will be used to support the revision of a guidance for industry on establishing pregnancy exposure registries.

Dates and Times: The meeting will be held on May 28, 2014, from 8 a.m. to 5 p.m. and May 29, 2014, from 8:30 a.m. to 12:30 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*. Please arrive early to ensure time for parking and security screening.

Contact Persons: For meeting background and content: Vicki Moyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6148, FAX: 301–796–9855, *vicki.moyer@fda.hhs.gov. For registration, oral presentations, special accommodations, and other meeting logistics:* Cherice Holloway, Center for