www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lucinda Buhse, Center for Drug Evaluation and Research, Food and Drug Administration, 1114 Market St., Suite 1002, St. Louis, MO 63101, 314–539–2134; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Analytical Procedures and Methods Validation for Drugs and Biologics.'' This revised draft guidance supersedes the 2000 draft guidance for industry on ''Analytical Procedures and Methods Validation'' and, when finalized, will also replace the 1987 FDA guidance for industry on ''Submitting Samples and Analytical Data for Methods Validation.'' It discusses how to submit analytical procedures and methods validation data to support the documentation of the identity, strength, quality, purity, and potency of drug substances and drug products and how to assemble information and present data to support analytical methodologies. The recommendations in this guidance apply to new drug applications, abbreviated new drug applications, biologics license applications, and supplements to these applications. The principles in this revised draft guidance also apply to Type II drug master files. This draft guidance does not address investigational new drug application (IND) methods validation specifically, but the principles being discussed may be helpful to sponsors preparing INDs.

This draft guidance complements the International Conference on Harmonisation guidance ''Q2(R1) Validation of Analytical Procedures: Text and Methodology.''

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on analytical procedures and methods validation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 211, 21 CFR part 314, and 21 CFR part 601 have been approved under OMB control numbers 0910–0139, 0910–0001, and 0910–0338.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or *http://www.regulations.gov.*

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03580 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–2013–N–1041]

Fibromyalgia Public Meeting on Patient-Focused Drug Development; Rescheduling of Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; rescheduling of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is rescheduling a December 10, 2013, public meeting on Patient-Focused Drug Development for fibromyalgia, announced in the **Federal Register** on September 23, 2013. Due to inclement weather, the Federal Government was closed on December 10, 2013. We are rescheduling the public meeting to March 26, 2014, and extending the comment period for the public docket.

DATES: The public meeting will be held on March 26, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by March 20, 2014. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit either electronic or written comments by May 27, 2014.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Sections B and C of the Great Room (rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm363203.htm.*

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1199, Silver Spring, MD 20993, 301–796–5003, FAX: 301–847–8443, email: *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2013 (78 FR 58313), FDA announced a public meeting on December 10, 2013, to obtain patients' perspectives on the impact of fibromyalgia on daily life as well as the available therapies for fibromyalgia. Due to the Government closure on December 10, 2013, the meeting was postponed. We are rescheduling the public meeting to March 26, 2014, and extending the comment period to May 27, 2014 (see

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