clinical investigators, of IRB, and of research sponsors.

Date and Time: The conference will be held on March 11 and 12, (Wednesday and Thursday) 2015, from 8:00 a.m. to 5 p.m.

Location: The conference will be held at the Holiday Inn Golden Gateway Hotel, 1500 Van Ness Ave., San Francisco, CA 91409, 415–441–4000.

Attendees are responsible for their own accommodations. Please mention SOCRA to receive the hotel room rate of $159.00 plus applicable taxes (available until February 13, 2015, or until the SOCRA room block is filled).

Contact Person: Jane Kreis, Food and Drug, Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739 or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914. 800–762–7292 or 215–822–8644, FAX: 215–822–8633, email: *Office@socra.org* Web site: *www.socra.org.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SOCRA member—$575, SOCRA nonmember (includes membership)—$650, Federal Government member—$450.00, Federal Government nonmember—$525.00, FDA Employee—(free) Fee Waived.

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

Extended periods of question and answer and discussion have been included in the program schedule. SOCRA designates this education activity for a maximum of 13.3 Continuing Education Credits for SOCRA continuing education (CE) and Nurse continuing nurse education (CNE), SOCRA designates this live activity for a maximum of 13.3 *American Medical Association Physician's Recognition Award* Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation. Continuing medical education (CME) for Physicians: SOCRA is accredited by the Accreditation Council for Continuing Medical Education to provide CME for physicians. CNE for Nurses: Society of Clinical Research Associates is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

Registration Instructions: To register, please submit a registration form with your name, affiliation, mailing address, telephone, FAX number, and email, along with a check or money order payable to ''SOCRA''. Mail to: SOCRA(see Contact Person for address). To register via the Internet, go to *http://www.socra.org/html/FDA_Conference.htm.* Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the workshop, contact SOCRA (see Contact Person).

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related informed consent, clinical investigation requirements, institutional review board inspections, electronic record requirements, and investigator initiated research Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial: (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with the FDA—Why, When and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03118 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Orthopaedic and Rehabilitation Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 20, 2015, from 8 a.m. to 6 p.m.

Location: Hilton/Washington DC North, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Sara Anderson, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1643, Silver Spring, MD 20993–0002, *sara.anderson@fda.hhs.gov,* 301–796–7047, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot

always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 20, 2015, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the Superion InterSpinous Spacer device sponsored by Vertiflex Inc. The proposed indication for use for the Superion InterSpinous Spacer device, as stated in the PMA, is as follows: The Superion InterSpinous Spacer (the Superion ISS) is intended to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without grade 1 spondylolisthesis, confirmed by x ray, magnetic resonance imaging, and/or computed tomography evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superion ISS may be implanted at one or two adjacent lumbar (L) levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

The meeting was originally scheduled for December 12, 2014. The meeting date is being postponed from December 12, 2014, until February 20, 2015, due to FDA needing additional time to review information supplied by sponsor.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 18, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 17, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Anne Marie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the February 20, 2015, Orthopaedic and Rehabilitation Panel of the Medical Devices Advisory Committee meeting. Because the Agency believes there is some urgency to bring these issues to public discussion and qualified members of the Orthopaedic and Rehabilitation Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *February 10, 2015.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03155 Filed 2–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Food and Drug Administration/Xavier University Global Medical Device Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled ''FDA/Xavier University Global Medical Device Conference (MedCon).'' This 3-day public conference includes presentations from key FDA officials and industry experts with small group breakout sessions. The conference is intended for companies of all sizes and employees at all levels.

DATES: *Dates and Times:* The public conference will be held on May 6, 2015, from 8:30 a.m. to 5 p.m.; May 7, 2015, from 8:30 a.m. to 5 p.m.; and May 8, 2015, from 8:30 a.m. to 12:30 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513–745–3016.

Contact Persons: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, FAX: 513–679–2771, email: *gina.brackett@fda.hhs.gov.*

For information regarding the conference and registration: Mason Rick, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3016, email: *rickm@xavier.edu,* or visit *http://www.XavierMedCon.com.*

Registration: There is a conference registration fee which covers the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the conference. Advanced registration begins February 6, 2015. Standard registration begins March 6, 2015. There will be onsite registration. The cost of registration is as follows: