

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 Superior InterSpinous Spacer device sponsored by Vertiflex Inc. The proposed indication for use for the Superior InterSpinous Spacer device, as stated in the PMA, is as follows: The Superior InterSpinous Spacer (the Superior 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 Superior 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 Superior 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](mailto: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]

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## 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](mailto: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](mailto: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:

TABLE 1—REGISTRATION FEES <sup>1</sup>

Attendee type	Advanced rate (2/6/15 to 3/5/15)	Standard rate (after 3/5/15)
Industry .....	\$1,495	\$1,695
Small Business (<100 Employees) .....	1,000	1,200
Startup Manufacturer .....	250	300
Academic .....	250	300
FDA/Government Employee .....	Free	Free

<sup>1</sup> The following forms of payment will be accepted: American Express, Visa, MasterCard, and company checks.

To register online for the public conference, please visit the “Registration” link on the conference Web site at <http://www.XavierMedCon.com>. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

To register by mail, please send your name, title, firm name, address, telephone, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207–5471. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Hilton Cincinnati Netherland Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513–421–9100. Special conference block rates are available through April 16, 2015. To make reservations online, please visit the “Venue/Logistics” link at <http://www.XavierMedCon.com>.

If you need special accommodations due to a disability, please contact Mason Rick (see *Contact Persons*) at least 7 days in advance of the conference.

**SUPPLEMENTARY INFORMATION:** The public conference helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Center Director Corner: Strategic Priorities for 2015 and Beyond
- Office of Compliance Strategic Priorities
- Advancements in Medical Device Software Technology
- Understanding and Preparing for the Revision of ISO13485
- Update from FDA’s Office of Combination Products
- Unique Device Identification—Implementation
- FDA Inspections and Insights
- Understanding the Current Activities of the International Medical Device Regulators Forum

- European Union Medical Device/In Vitro Diagnostics Regulation Review
- Update from the Office of Device Evaluation
- Regulatory Submissions and Strategies
- Complaints, Corrective and Preventive Actions, and Recalls
- Regulatory Challenges in Asia
- Action Plan Writing
- Lunch Networking by Topic

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 conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration 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 conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) by providing outreach activities by Government agencies to small businesses.

Dated: February 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–03116 Filed 2–13–15; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2015–N–0001]

### In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

The Food and Drug Administration (FDA) Detroit District Office, in sponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public conference entitled “In Motion: Science Transforming

Policy in Food, Drug, and Medical Device Regulation.” The conference Web site is <http://indy.afdo.org/>. This conference is intended to provide information about FDA food, drug, and device regulation to the regulated industry.

**Date and Time:** The public conference will be held on June 20 to 24, 2015. Times will vary.

**Location:** The conference will be held at the Sheraton Indianapolis Hotel at Keystone Crossing, Indianapolis, 8787 Keystone Crossing, Indianapolis, IN 46240, 317–846–2700 or toll-free 888–627–7814; [www.sheratonindianapolis.keystonecrossing.com](http://www.sheratonindianapolis.keystonecrossing.com).

Attendees are responsible for their own accommodations. To make reservations at the Sheraton Indianapolis Hotel at the reduced conference rate, please call 303–295–1234 and mention “AFDO Conference” before May 20, 2015. All the hotel information needed to call or reserve online is available at <http://indy.afdo.org/hotel.html>.

**AFDO contact information:** Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., suite 311, York, PA 17402, 717–757–2888, FAX: 717–650–3650, email: [ryoung@afdo.org](mailto:ryoung@afdo.org).

**Registration:** You are encouraged to register by May 20, 2015. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the conference beginning at 8 a.m. The cost of registration follows:

Cost of Registration:

Member—\$475.00

Non-Member—\$575.00

\*A \$100 late fee will be added if payment is postmarked after June 1, 2015.

If you need special accommodations due to a disability, please contact Randy Young (see *AFDO contact information*)