4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Food and Drug Administration/Xavier University Global Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: 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 and Times: The public conference will be held on May 7, 2014, from 8:30 a.m. to 5 p.m.; May 8, 2014, from 8:30 a.m. to 5 p.m.; and May 9, 2014, from 8:30 a.m. to 12:45 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073 or 513-745-3020.

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: Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, email: phillipsm4@xavier.edu.

Registration: There is a registration fee. The conference registration fees cover the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the

conference. Early registration ends March 11, 2014. Advanced registration rates begin March 12, 2014. Standard registration rates begin April 9, 2014. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Early Rate (through 3/11/14)	Advanced Rate (3/12/14 to 4/8/14)	Standard Rate (4/9/14 to 5/9/14)
Industry	$1,195	$1,495	$1,695
Small Business (<100 employees)	$900	$1,000	$1,200
Startup Manufacturer	$200	$250	$300
Academic	$200	$250	$300
FDA/Government Employee	Fee Waived	Fee Waived	Fee Waived

[1]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 and fax numbers, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Parkway, Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Cincinnati Hilton Netherlands Plaza, 35 West 5th Street, Cincinnati, OH, 45202, 513-421-9100. Special conference block rates are available through April 16, 2014. 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 Marla Phillips (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 for Devices and Radiological Health Future Vision and Strategy Keynote Address;
- European Union Regulations: New Regulations, Company Strategy, and Open Discussion Forum;
- How to Implement the Unique Device Identification Requirements;
- Update from the Office of Device Evaluation;
- FDA Regulation of Health Information Technology: Medical Apps, Cybersecurity, and "the Cloud";
- Managing Scientific and Regulatory Disagreement;
- Combination Products;
- FDA Inspectional Approach--Panel with current FDA investigators;
- Operationalizing Post-Market Surveillance;
- 510(k) Process;
- Risk Management;
- Purchasing Controls;
- Office of Compliance Update; and
- Strategic Thinking on Access in China.

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 (Pub. L. 104-121) by providing outreach activities by Government Agencies to small businesses.

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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