4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-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." 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.

Date and Time: The public conference will be held on May 1, 2013, from 8:30 a.m. to 5 p.m.; May 2, 2013, from 8:30 a.m. to 5 p.m.; and May 3, 2013, from 8:30 a.m. to 1 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 513-745-3396.

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,

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,

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 13, 2013. Standard registration ends April 9, 2013. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Advanced Rate (March 13, 2013 to April 8, 2013)	Standard Rate (April 9, 2013 to May 3, 2013)
Industry	$1,295	$1,495
Small Business (<100 employees)	$900	$1,000
Consultant	$600	$700
Startup Manufacturer	$250	$300
Academic	$250	$300
FDA/Government Employee	Free	Free

[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 "Register Now" 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: Sue

Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West Fifth St., Cincinnati, OH, 45202, 513-421-9100. Special Conference Block rates are available through April 9, 2013. 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:

- CDRH Future Vision and Strategy Keynote Address
- U.S. Congressman Erik Paulsen Keynote Dinner
- EU Regulations: New Regulations, Company Strategy, and Open Discussion Forum
- FDA Safety and Innovation Act
- Unique Device Identification
- Update from the Office of Device Evaluation
- Total Product Life Cycle: Interactive Workshop
- Pre-Submission Program and Meetings with the FDA
- 510(k): New FDA Guidance and Industry Regulations
- PMAs: New Guidance and Compliance Initiatives
- Software and Mobile Apps

- Combination Products
- Entering the EU Market and CE Mark Hot Topics
- Global Product Strategy
- Success in Central and South America
- FDA Inspectional Approach--Panel with Current FDA Investigators

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: March 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-05727 Filed 03/12/2013 at 8:45 am; Publication Date: 03/13/2013]