4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-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, and has two separate tracks of interest. 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 2, 2012, from 8:30 a.m. to 5 p.m.; May 3, 2012, from 8:30 a.m. to 5 p.m.; and May 4, 2012, 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: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, ext. 2167, 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, lunches, and dinners for the 3 days of the conference. Early registration ends March 6, 2012. Standard registration ends March 27, 2012. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee	Fee by March 6th	Fee by March 27th
Industry	$995	$1,295
Small Business (<100 employees)	$800	$900
Consultant	$500	$600
Academic	$200	$250
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 "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: 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 headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH, 45202, 513-421-9100. Special conference block rates are available through April 11, 2012. 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 Medical Device Innovation Initiative Keynote Address;
- 510(k)--Office of Device Evaluation Perspective;
- The Purchasing Control Subsystem--Requirements and Implementation;
- Draft 510(k) Guidance--Deciding When to Submit a 510(k) for a Change or Modification;
- Challenges of Design Controls;
- FDA 483s and Regulatory Action--Response Workshop;
- Recalls--Globally;
- GHTF Document on CAPA--Workshop;
- 510(k)--An Industry Perspective;
- Interdependency of Postmarket Surveillance, Risk, and CAPA;
- Promotional Practices--Global;
- Office of Compliance Initiatives;
- U.S. Senate HELP Committee Keynote Dinner;
- Risk Management Across the Quality Systems--FDA Expectations and Implementation;
- Global Regulatory Strategy; and
- 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 (Public Law 105-115) (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 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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