DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Food and Drug Administration/Xavier Medical Device Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

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

DATES: The public conference will be held on May 4, 2016, from 8:30 a.m. to 5 p.m.; May 5, 2016, from 8:30 a.m. to 5 p.m.; and May 6, 2016, from 8:30 a.m. to 12:05 p.m.

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

FOR FURTHER INFORMATION CONTACT: *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, Program Manager, Xavier Health, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3016, email: *rickm@xavier.edu* or visit *http://www.XavierMedCon.com.*

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:

- Update from FDA's Office of Combination Products
- Center Director Corner: Strategic Priorities for 2016 and Beyond
- Office of Compliance Strategic Priorities
- Medical Device Innovation Consortium (MDIC)/Xavier University Medical Device Metrics Initiative
- Critical Thinking—Responding to FDA
- Working Through Challenges with Supplier Quality and Design—What to Do and When
- FDA Inspections and Insights
- Canada's Changing Quality System Requirements
- European Medical Device Regulation Progress
- Update from the Office of Device Evaluation
- What to Expect with FDA's Program Alignment
- When to File a 510(k) for Modifications to Your Cleared Device
- Storing Clinical Data in the Cloud
- Regulatory Strategy for Innovation
- Internet and Social Media Concerns—FDA and Federal Trade Commission (FTC) Perspectives
- Navigating Japan's Regulatory Environment
- 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 (Pub. L. 104–121) by providing outreach activities by Government Agencies to small businesses.

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 rates end February 3, 2016. Advance registration rates end on March 3, 2016. Standard registration rates begin March 4, 2016. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES [1]

Attendee type	Early rate (through 2/3/16)	Advance rate (2/4/16–3/3/16)	Standard rate (after 3/3/16)
Industry	$1,195	$1,495	$1,695
Small Business (<100 employees)	900	1,000	1,200
Start-up Manufacturer	200	250	300
Academic	200	250	300
FDA/Government Employee	Free	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, email, and payment information for the fee to Xavier University, Attn: 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 headquarter hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 W. 5th St., Cincinnati, OH 45202, 513–421–9100. Special conference block rates are available through April 11, 2016. 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 **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

Dated: January 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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