DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Food and Drug Administration/Xavier University Medical Device Conference (MedCon)

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 University 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 3 and 4, 2017, from 8:30 a.m. to 5:00 p.m.; May 5, 2017, from 8:30 a.m. to 12:30 p.m., at the University of Cincinnati, 3800 Victory Pkwy., Cincinnati, OH 45207–5416.


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 the Office of Device Evaluation.
- FDA Insight on the 510(k) Modifications Guidance.
- 510(k) Modifications: To submit or not to submit?
- Your Contract Manufacturer Received a Warning Letter. What Now?
- Defending Claims for Your Device.
- The Impact of Cultural Misalignment . . . and the Path Forward.
- The Importance of Quality and Regulatory throughout the Merger and Acquisition Lifecycle—Landmines or Opportunities.
- What to Expect with FDA’s Program Alignment?
- Investigator Insights and Breaking News.

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. There will be on-site registration. The cost of registration is as follows:

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<thead>
<tr>
<th>Attendee type</th>
<th>Standard rate</th>
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<tbody>
<tr>
<td>Industry</td>
<td>$1,695</td>
</tr>
<tr>
<td>Small Business (&lt;100 employees)</td>
<td>$1,200</td>
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<tr>
<td>Start-up Manufacturer</td>
<td>$300</td>
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<tr>
<td>Academic</td>
<td>$300</td>
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<tr>
<td>FDA/Government Employee</td>
<td>Free</td>
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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 to the Mayo Clinic, 200 First Street SW, Rochester, MN 55905. Attn: Anuj Shah. Special conference block rates are available through April 11, 2017.

FOR FURTHER INFORMATION CONTACT: Anuj Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–796–3318.