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, 2017, from 8:30 a.m. to 5 p.m.; May 4, 2017, from 8:30 a.m. to 5 p.m.; and May 5, 2017, from 8:30 a.m. to 12:30 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: Marla Phillips, Xavier Health, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207–5471, 513–745–3073, email: *phillipsm4@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:

- Center Director Corner: Strategic Priorities for 2017 and Beyond.
- European Union (EU) Regulations—Exploring the Unknown.
- Impact of the New EU Regulations on Your Global Regulatory Strategy.
- Digital Health—Key Focus Areas for FDA and Industry.
- Office of Compliance Strategic Priorities.
- 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 onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES[1]

Attendee type	Standard rate
Industry	1,695
Small Business (<100 employees)	1,200
Start-up Manufacturer	$300
Academic	$300
FDA/Government Employee	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, Attention: Marla Phillips, 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 West 5th St., Cincinnati, OH, 45202, 513–421–9100. Special Conference Block rates are available through April 11, 2017. 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 **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the conference.

Dated: March 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–P–3560]

Determination That CEDAX (Ceftibuten Dihydrate) for Oral Suspension, 90 Milligrams/5 Milliliters and 180 Milligrams/5 Milliliters, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that CEDAX (ceftibuten dihydrate) for oral suspension, 90 milligrams (mg)/5 milliliters (mL) and 180 mg/5 mL, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for ceftibuten dihydrate for oral suspension, 90 mg/5 mL and 180 mg/5 mL, if all other legal and regulatory requirements are met.

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, 301–796–2246.