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.

[FR Doc. 2017–06699 Filed 4–4–17; 8:45 am]

BILLING CODE 4164–01–P

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.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, are the subject of NDA 050686, held by Pernix Therapeutics LLC, and initially approved on December 20, 1995. CEDAX is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of *Haemophilus influenzae* (including β-lactamase-producing strains), *Moraxella catarrhalis* (including β-lactamase-producing strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains only) in acute bacterial exacerbations of chronic bronchitis; *H. influenzae* (including β-lactamase-producing strains), *M. catarrhalis* (including β-lactamase-producing strains), or *S. pneumoniae* (penicillin-susceptible strains only) in acute bacterial otitis media; and *S. pyogenes* in pharyngitis and tonsillitis.

CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Orchid Healthcare (a division of Orchid Pharma, Ltd.) submitted a citizen petition dated October 26, 2016 (Docket No. FDA–2016–P–3560), under 21 CFR 10.30, requesting that the Agency determine whether CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 30, 2017.

Anna K. Abram,

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

[FR Doc. 2017–06701 Filed 4–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering.

Date: May 18, 2017.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Report from the Institute Director, other Institute Staff and scientific presentation.

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Closed: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: David T. George, Ph.D., Acting Associate Director, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 920, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nibib1.nih.gov/about/NACBIB/*