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 45207–5416.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–421–9100. 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 FDA’s and industry’s important mission to ensure safety and effectiveness. This determination will be 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:

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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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1 The following forms of payment will be accepted: American Express, Visa, MasterCard, and company checks.

To register 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 headquarters hotel is the Downtown Cincinnati Hilton Netherlands Plaza, 35 West 5th St., Cincinnati, OH, 45202. 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.


Anna A. 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
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 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.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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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: Devon Ramsey, 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.nihbi1.nih.gov/about/NACBIB/