

Cincinnati, OH 45207, 513-745-3073 or 513-745-3396.

**Contact Persons:**

*For information regarding this notice:*

Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, ext 167, FAX: 513-679-2772, e-mail: [gina.brackett@fda.hhs.gov](mailto:gina.brackett@fda.hhs.gov).

*For information regarding the conference and registration:* Marla Phillips, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3073, e-mail: [phillipsm4@xavier.edu](mailto:phillipsm4@xavier.edu).

*Registration:* There is a registration fee. The conference registration fees

cover the cost of the presentations, training materials, receptions, breakfasts, lunches, and dinners for the 3 days of the conference. Early registration ends April 3, 2011. Standard registration ends May 2, 2011. There will be onsite registration. The cost of registration is as follows:

TABLE 1—REGISTRATION FEES

Attendee	Fee by April 3, 2011	Fee by May 3, 2011
Industry .....	\$995	\$1,200
Small Business (<100 employees) .....	800	1,000
Academic .....	600	750
FDA/Government Employee .....	140	140

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 and fax numbers, e-mail, and payment information for the fee to Xavier University, Attention: Sue Bensman, 3800 Victory Pkwy., Cincinnati, OH 45207. An e-mail 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 12, 2011. 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 *Contact Persons*) at least 7 days in advance of the conference.

**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:

- Changes Within the Center for Devices and Radiological Health (CDRH) That Will Impact Our Industry.
- 510(k) Changes: Panel Discussion.
- Combination Products Panel.

- Update on Quality System Regulations. Warning Letter and Enforcement Action Trends.
- MDUFMA Legislation.
- Corrective and Preventive Actions.
- Clinical Data Requirement Changes—Premarket Clearance.
- Reimbursement Panel.
- MDR Reporting/Vigilance.
- Ethical Issues Leading to Non-Compliance In Clinical Trials.
- Risk Management and Design Controls.
- 510(k) SE Decision Making Process.
- Warning Letter Trends for Sponsor-Monitors and CRO’s.
- Supplier Controls.
- Advertising, and Promotion and Labeling Pre- and Post-Market.
- Ensuring Site Compliance in Clinical Trials.
- FDA’s Bioresearch Monitoring Program—Overview and Current Activities.
- Inspection Readiness.
- Training.
- International Regulatory Update.
- FDCA, Anti Kickback and False Claims Act, Implications of Investigator-Initiated Trials.
- Recalls, Requirements and Challenges.
- CE Mark.
- Adverse Event Reporting During Clinical Investigation in the EU.
- Clinical Evaluation for EU Market Access.
- Using Electronic Medical Records.
- Cooperative Research Activities Between Academia and Industry.

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.

Dated: March 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Amended Notice of Establishment**

Notice is hereby given as a correction in the announcement of the establishment of the NCI-Frederick Advisory Committee, which was published in the **Federal Register** on March 15, 2011, 75 FR 14035.

This FRN is amended to replace the word “Council” used in the second paragraph to the word “Committee”.

Dated: March 16, 2011.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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