TABLE 1—REGISTRATION FEES [1]

Attendee type	Advanced rate (2/6/15 to 3/5/15)	Standard rate (after 3/5/15)
Industry	$1,495	$1,695
Small Business (<100 Employees)	1,000	1,200
Startup Manufacturer	250	300
Academic	250	300
FDA/Government Employee	Free	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: Mason Rick, 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 Hilton Cincinnati Netherland Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513–421–9100. Special conference block rates are available through April 16, 2015. 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 Mason Rick (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:

- Center Director Corner: Strategic Priorities for 2015 and Beyond
- Office of Compliance Strategic Priorities
- Advancements in Medical Device Software Technology
- Understanding and Preparing for the Revision of ISO13485
- Update from FDA's Office of Combination Products
- Unique Device Identification—Implementation
- FDA Inspections and Insights
- Understanding the Current Activities of the International Medical Device Regulators Forum
- European Union Medical Device/In Vitro Diagnostics Regulation Review
- Update from the Office of Device Evaluation
- Regulatory Submissions and Strategies
- Complaints, Corrective and Preventive Actions, and Recalls
- Regulatory Challenges in Asia
- Action Plan Writing
- Lunch Networking by Topic

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 (Public Law 104–121) by providing outreach activities by Government agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–03116 Filed 2–13–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) Detroit District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public conference entitled ''In Motion: Science Transforming Policy in Food, Drug, and Medical Device Regulation.'' The conference Web site is *http://indy.afdo.org/.* This conference is intended to provide information about FDA food, drug, and device regulation to the regulated industry.

Date and Time: The public conference will be held on June 20 to 24, 2015. Times will vary.

Location: The conference will be held at the Sheraton Indianapolis Hotel at Keystone Crossing, Indianapolis, 8787 Keystone Crossing, Indianapolis, IN 46240, 317–846–2700 or toll-free 888–627–7814; *www.sheratonindianapoliskeystonecrossing.com.*

Attendees are responsible for their own accommodations. To make reservations at the Sheraton Indianapolis Hotel at the reduced conference rate, please call 303–295–1234 and mention ''AFDO Conference'' before May 20, 2015. All the hotel information needed to call or reserve online is available at *http://indy.afdo.org/hotel.html.*

AFDO contact information: Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., suite 311, York, PA 17402, 717–757–2888, FAX: 717–650–3650, email: *ryoung@afdo.org.*

Registration: You are encouraged to register by May 20, 2015. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the conference beginning at 8 a.m. The cost of registration follows:

Cost of Registration:

Member—$475.00
Non-Member—$575.00

*A $100 late fee will be added if payment is postmarked after June 1, 2015.

If you need special accommodations due to a disability, please contact Randy Young (see *AFDO contact information*)

at least 21 days in advance of the conference.

Registration Instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO''. Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register online, please visit *http://indy.afdo.org/register.html.* (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**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the conference, or for questions about registration, please contact AFDO at 717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include, but are not limited to, the following:

- Medical Device Single Audit Program
- Contract Manufacturing Arrangements for Drugs: Quality Agreements
- Compliance Question and Answer Panel
- Draft Guidance: Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements
- Compounding Pharmacies
- Overview of Global Device/Drug Requirements v. U.S. System
- Case for Quality Initiative Update
- Unique Device Identifier (UDI) Implementation Update
- Metric, Data, and Analysis; Biometrics
- Pharmaceutical Inspection Cooperation Scheme
- Biosimilar Regulations

FDA has made education of the food, feed, drug, and device manufacturing community a high priority to help ensure the quality of FDA-regulated products. 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), as outreach activities by government agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0824]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry, including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by March 19, 2015. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT: Loni Warren Henderson, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 240–402–7800, FAX: 301–595–1243, *Industry.Biologics@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005. Through these annual notices, CBER is requesting that those firms that have previously applied and are still interested in participating reaffirm their interest. CBER is also requesting that new interested parties apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits.