4164-01-P

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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