4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

The Food and Drug Administration and Global Engagement: Progress on the Pathway to Global Product Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

Summary: The Food and Drug Administration (FDA) Denver District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), will be hosting the 118th AFDO Annual Educational Conference. During the conference, a 2-day public workshop will be held entitled "FDA and Global Engagement: Progress on the Pathway to Global Product Safety," This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

Dates and Times: The conference will be held from June 21 through June 25. The public workshop, "FDA and Global Engagement: Progress on the Pathway to Global Product Safety," will be held on June 23 and 24, 2014, from 10:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Grand Hyatt Denver, 1750 Welton St., Denver, CO 80202, 1-303-295-1234 or toll free 800-233-1234; http://granddenver.hyatt.com. Attendees are responsible for their own accommodations. To make reservations at the Grand Hyatt Denver at the reduced conference rate, please go to https://resweb.passkey.com/go/afdo2014 or call 1-303-295-1234 and mention "AFDO Conference" before May 21, 2014.

AFDO Contact Information: Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., Suite 311, York, PA 17402, 1-717-757-2888, FAX: 717-650-3650, ryoung@afdo.org.

Registration: You are encouraged to register by May 23, 2014. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Public workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. Registration will close after the public workshop is filled. Registration at the site is not guaranteed but may be possible on a space-available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

Cost of Registration*	
ADFO Member	$475.00
Non-ADFO Member	$575.00

*A $100 registration fee will be added if payment is postmarked after June 1, 2014.

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 workshop.

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://www.afdo.org/conference. (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 public workshop, or for questions about registration, please contact AFDO at 1-717-757-2888, FAX: 717-650-3650, or email: afdo@afdo.org.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop 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 vs. U.S. System;
- Case for Quality Initiative Update;
- Unique Device Identifier Implementation Update;
- Metric, Data, and Analysis; Biometrics;
- Pharmaceutical Inspection Cooperation Scheme; and
- 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 public workshop 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 workshop 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: March 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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