



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0757]

Pathways to Global Unity; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the Association of Food and Drug Officials (AFDO), is announcing the following public workshop entitled “Pathways to Global Unity.” This 2 1/2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industries.

DATES: The public workshop will be held on June 11-12, 2018, from 8 a.m. to 5:30 p.m., and on June 13, 2018, from 8 a.m. to 12 p.m.

ADDRESSES: The public workshop will be held at the Doubletree by Hilton Hotel Burlington Vermont, 870 Williston Rd., Burlington, VT 05403, 802-865-6626. For directions to the hotel and information on lodging, visit <http://burlington.afdo.org/hotel.html>. Attendees are responsible for their own accommodations.

FOR FURTHER INFORMATION CONTACT: Krystal Reed, Association of Food and Drug Officials, 155 West Market St., 3rd Floor, York, PA 17401, 717-757-2888, Fax: 717-650-3650, email: kreed@afdo.org.

SUPPLEMENTARY INFORMATION:

I. Background

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 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.

II. Topics for Discussion at the Public Workshop

The public workshop helps fulfill the Department of Health and Human Services and FDA's 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. The public workshop's agenda is available at <http://www.afdo.org/conference>. Topics for discussion include the following:

- FDA Associate Commissioner for Regulatory Affairs Update
- Health Canada: Single Audit Program
- Enforcement Trends in Drug, Devices, and Compounding Pharmacy Inspections
- FDA Compliance Questions Panel
- International Compliance--Industry Perspective
- Puerto Rico Emergency Response Update
- Artificial Intelligence
- Supply Chain Control

- Dermal Abyss: Tattoos as Medical Condition Monitors
- Design Controls for Combination Products
- Benefit Risk--Using Benefit Risk in Making Post-Market Decisions

III. Participating in the Public Workshop

Registration: You are encouraged to register by May 1, 2018. 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 public workshop beginning at 7:30 a.m. The cost of registration is as follows:

Category	Cost of Registration
AFDO Members	\$550
AFDO Non-Members	\$650
Additional Fee for Registration Postmarked After May 1, 2018	\$100

To register online, please visit <http://www.afdo.org/conference> (FDA has verified the website address, but is not responsible for subsequent changes to the website after this document publishes in the *Federal Register*.) For alternative registration, please complete and submit an AFDO Conference Registration Form, available at <http://burlington.afdo.org/registration.html>, along with a check or money order payable to AFDO. Please mail your completed registration form and payment to: AFDO, 155 West Market St., 3rd Floor, York, PA 17401. The registrar will also accept payment through Visa, MasterCard, and American Express credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 717-757-2888, afdo@afdo.org, or <http://www.afdo.org/conference>.

If you need special accommodations due to a disability, please contact Krystal Reed (see FOR FURTHER INFORMATION CONTACT) at least 21 days in advance of the workshop.

Dated: March 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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