



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Food Defense; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in co-sponsorship with Oklahoma State University (OSU), Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled “Food Defense Workshop.” This public workshop is intended to provide information about food defense as it relates to food facilities such as farms, manufacturers, processors, distributors, retailers, and restaurants.

Date and Time: This public workshop will be held on November 7 and 8, 2012, from 7:45 a.m. to 4:15 p.m.

Location: The public workshop will be held at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078-6055.

Contact: For information regarding the workshop: David Arvelo, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, email: david.arvelo@fda.hhs.gov.

For information on accommodations: Karen Smith or Andrea Graves at the Robert M. Kerr Food & Agricultural Products Center, Oklahoma State University, 148 FAPC, Stillwater, OK 74078-6055, 405-744-6277, FAX: 405-744-6313, or email: karenl.smith@okstate.edu or andrea.graves@okstate.edu. More information is also available online at <http://www.fapc.biz/fooddefense2012.html>.

Registration: You are encouraged to register by October 31, 2012. The workshop has a registration fee to cover the cost of facilities, materials, speakers, and breaks. The registration fee is \$350 for companies with 10 or more employees or \$250 for companies with less than 10 employees. Seats are limited; please submit your registration as soon as possible. To register, please complete the online registration form at <http://www.fapc.biz/fooddefense2012.html>. The workshop will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the 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 7:45 a.m. Make checks payable to: "FAPC." If you need special accommodations due to a disability, please contact Karen Smith (see Contact) at least 7 days in advance. There are no registration fees for FDA employees.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested after the date of the public workshop by contacting Karen Smith or Andrea Graves (see Contact) at cost plus shipping.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food defense inquiries from food manufacturers originating from

the area covered by the FDA Dallas District Office. The Southwest Regional Office presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Representative Program, which are, in part, to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government Agencies to small businesses.

The goal of this public workshop is to present information that will enable regulated industry to better comply with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and to better understand FDA's food defense guidance, especially in light of growing concerns about food protection. Information presented will be based on Agency position as articulated through regulation, guidance, and information previously made available to the public. Topics to be discussed at the workshop include the following:

- Food defense awareness and definitions,
- FDA food defense tools such as ALERT and Employees FIRST,
- Regulations mandated by the Bioterrorism Act,
- Food Defense Guidance from the Food Safety and Inspection Service,
- Investigating food-related incidents effectively,

- Physical plant security,
- Crisis management, and
- A food related emergency exercise bundle (FREE-B) tabletop exercise on food defense.

For more information, please visit <http://www.fapc.biz/fooddefense2012.html>. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency's regulatory and policy perspectives on food protection, increase compliance with FDA regulations, and heighten food defense awareness.

Dated: September 21, 2012.

Leslie Kux,
Assistant Commissioner for Policy.

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