Government agencies, employees' references, co-workers, neighbors, educational institutions, and intelligence sources. Security violation information is obtained from a variety of sources, such as security guard's reports, security inspections, witnesses, supervisor's reports, and audit reports.

**FILES EXEMPTED FROM PARTS OF THE ACT:**

Under 5 U.S.C. 552a(k)(5), the personnel security case files in the system of records are exempt from subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the act. Information will be withheld to the extent it identifies witnesses promised confidentiality as a condition of providing information during the course of the background investigation.

[FR Doc. E7–1866 Filed 2–5–07; 8:45 am]

**BILLING CODE 6820–34–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Food Defense Workshop; 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 the University of Arkansas (UA) Institute of Food Science and Engineering (IFSE), is announcing a public workshop entitled ''Food Defense Workshop.'' This public workshop is intended to provide information about food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and other related subjects to FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants).

*Date and Time*: This public workshop will be held on May 23 through 24, 2007, from 8 a.m. to 5 p.m.

*Location*: The public workshop will be held at the Continuing Education Center, 2 East Center St., Fayetteville, AR (located downtown).

*Contact*: 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, or e-mail: *david.arvelo@fda.hhs.gov*.

For information on accommodation options, contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science and Engineering, University of Arkansas, Fayetteville, AR 72704, 479–575–4221, FAX: 479–575–2165, or email: *seideman@uark.edu*.

*Registration*: You are encouraged to register by May 9, 2007. The University of Arkansas has a $150 registration fee to cover the cost of facilities, materials, speakers, and breaks. Seats are limited; 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 8 a.m. The cost of registration at the site is $200 payable to: ''The University of Arkansas.'' If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact* section of this document) at least 7 days in advance.

*Registration Form Instructions*: To register, please complete the following form and submit along with a check or money order for $150 payable to the ''The University of Arkansas.'' Mail to: Institute of Food Science and Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704.

FOOD DEFENSE WORKSHOP REGISTRATION FORM

| | |
|---|---|
| Name: | |
| Affiliation: | |
| Mailing Address: | |
| City: | State: |
| Zip Code: | |
| Phone: ( ) | |
| FAX: ( ) | |
| E-mail: | |
| Special Accommodations Required: | |

*Transcripts*: Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts may be requested at cost through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food defense concerns from FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants) 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, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance, requirements, and compliance policies. 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 FDA-regulated food facilities (farms, manufacturers, processors, distributors, retailers, and restaurants) to better comply with the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and with food defense guidance, especially in light of growing concerns about food defense. 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: (1) Food defense awareness, (2) ALERT: The basics, (3) FDA actions on bioterrorism legislation (food supply), (4) food recalls, (5) crisis management, (6) food defense technologies and methodologies, and other related topics. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food defense and increase voluntary compliance and food defense awareness.

Dated: January 31, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007D–0031]**

### Global Harmonization Task Force, Study Groups 1, 2, and 4; New Proposed and Final Documents; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Groups 1, 2, and 4 of the Global Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Groups that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. FDA is requesting comments on these documents.

**DATES:** Submit written or electronic comments on any of the proposed documents byMay 7, 2007. After May 7, 2007, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

**ADDRESSES:** Submit written requests for single copies of the documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

*For Study Group 1*: Ginette Y. Michaud, Chairperson, GHTF, Study Group 1, Office of Device Evaluation, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

*For Study Group 2*: Mary Brady, GHTF, Study Group 2, Office of Surveillance and Biometrics, Center for Devices and Radiological Health (HFZ–530), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3458.

*For Study Group 4*: Jacqueline Welch, GHTF, Study Group 4, Office of Compliance, Center for Devices and Radiological Health (HFZ–320), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0115.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by three of the Study Groups (1, 2, and 4).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of its efforts, this group has developed proposed document SG1(PD)N044:2006. SG1(PD)N044:2006 (proposed document), entitled ''Role of Standards,'' provides guidance on the use of standards by a manufacturer when designing a medical device and, subsequently, when demonstrating the device conforms to relevant essential safety and performance criteria. FDA seeks comment on the document and particularly ''Section 5.2 Revision or Replacement of Recognised Standards.'' This section addresses the use of a recognized standard during the transitional period when it is being replaced by a revised version.

Study Group 4 was initially tasked with the responsibility of developing