

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 1

[Docket Nos. 2002N-0276 and 2002N-0278]

### Final Regulations Implementing Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Notice of Public Meeting

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

**ACTION:** Notice; satellite downlink public meeting.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting (via satellite downlink) to discuss final regulations implementing two sections in Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) regarding Registration of Food Facilities (Docket No. 2002N-0276) and Prior Notice of Imported Food Shipments (Docket No. 2002N-0278). FDA expects to publish shortly in the **Federal Register** final rules implementing each of these provisions. The purpose of the satellite downlink public meeting is to provide information on the rules to the public and to provide the public an opportunity to ask questions of clarification.

**DATES:** The satellite downlink public meeting will be held on Tuesday, October 28, 2003, from 1 p.m. to 3 p.m. eastern standard time. Questions submitted in advance must be received by the contact person by close of business (4:30 p.m.) on Friday, October 24, 2003.

**ADDRESSES:** See **SUPPLEMENTARY INFORMATION** for locations where the satellite downlink may be viewed. A written transcript of the meeting will be available for viewing at the Division of Dockets Management (DDM) (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and through the Web site at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

A copy of the videotaped meeting may also be viewed at DDM.

**FOR FURTHER INFORMATION CONTACT:** Louis J. Carson, Center for Food Safety and Applied Nutrition (HFS-32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2277, FAX: 301-436-2605, e-mail: [CFSAN-FSS@cfsan.fda.gov](mailto:CFSAN-FSS@cfsan.fda.gov), for general questions about the downlink, submission of advance questions, and requests for a videotaped version of the meeting. Registration for specific downlink locations should be directed to the appropriate contact person listed in table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes four provisions in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A (Protection of Food Supply) that require the Secretary of Health and Human Services, through FDA, to develop implementing regulations on an expedited basis. These four provisions are section 305 (Registration of Food Facilities); section 307 (Prior Notice of Imported Food Shipments); section 306 (Maintenance and Inspection of

Records for Foods); and section 303 (Administrative Detention). FDA expects that the agency will soon publish in the **Federal Register** final rules to implement sections 305 and 307 of the Bioterrorism Act. During the satellite downlink public meeting, FDA will explain the final rules on registration of food facilities and prior notice of imported food shipments and will answer questions. The satellite downlink public meeting will be offered in English with French and Spanish translation, and will be simulcast live in English, French, and Spanish for Mexico and North, Central, and South America (including Hawaii and Alaska).

## **II. Submitting Questions**

Interested persons may submit questions concerning the final rules in advance of the downlink meeting. The deadline for the submission of questions is provided in the **DATES** section of this document. Questions submitted in advance will be used by the session moderator to help clarify issues of concern and provide information about the final rules. The viewing audience may telephone or fax questions to the FDA participants during the live downlink.

FDA is planning a second satellite downlink meeting during which FDA will explain the final rules that FDA intends to publish later this year to implement sections 306 and 303 of the Bioterrorism Act. That meeting will be announced in a future **Federal Register** document.

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction may be found on the agency's Web site, *<http://www.fda.gov/oc/bioterrorism/bioact.html>*.

## **III. Final Rules**

The final regulations that will be addressed at the satellite downlink public meeting announced in this document concern the following provisions of the Bioterrorism Act:

Section 305: Registration of Food Facilities—The Bioterrorism Act requires the owner, operator, or agent-in-charge of domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA no later than December 12, 2003. Farms, restaurants, retail food establishments, non-profit food establishments that prepare or serve food directly to the consumer, and fishing vessels not engaged in processing, as defined in 21 CFR 123.3(k), are exempt from this requirement. Also exempt are foreign facilities if the food from the facility undergoes further processing or packaging of more than a de minimus nature by another facility outside of the United States. FDA must issue final regulations no later than December 12, 2003, but facilities must register by this date in accordance with the Bioterrorism Act even if the regulations are not finalized. FDA plans to publish a registration final rule by October 10, 2003.

Section 307: Prior Notice of Imported Food Shipments—The Bioterrorism Act specifies that on or after December 12, 2003, FDA must receive prior notice of each article of food imported or offered for import into the United States. FDA must issue the final regulation by December 12, 2003. If the regulation is not final by that date, the Bioterrorism Act still requires FDA to receive prior notice of not less than 8 hours and not more than 5 days until the regulation takes effect. The agency plans to publish a prior notice final rule by October 10, 2003.

**IV. Sites for Viewing the Downlink Public Meeting**

A list of locations for viewing the downlink public meeting is provided in table 1 of this document.

TABLE 1.—OCTOBER 28, 2003, SATELLITE DOWNLINK PUBLIC MEETING I—SECTION 305: REGISTRATION OF FOOD FACILITIES AND SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

Locations	Contact Information
FDA New York District Office, 158–15 Liberty Ave., Jamaica, NY 11433	Marilyn Corretto, 718–662–5461; FAX: 718–662–5434; e-mail: <a href="mailto:mcorrett@ora.fda.gov">mcorrett@ora.fda.gov</a>

TABLE 1.—OCTOBER 28, 2003, SATELLITE DOWNLINK PUBLIC MEETING I—SECTION 305: REGISTRATION OF FOOD FACILITIES AND SECTION 307: PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS—Continued

Locations	Contact Information
FDA Buffalo Office, 300 Pearl St., Buffalo, NY 14202	Robert Hart, 716–551–4461 X3142; FAX: 716–551–3813; e-mail: <a href="mailto:Rhart@ora.fda.gov">Rhart@ora.fda.gov</a>
Plattsburgh Area, Angell Center, Plattsburgh Room, Plattsburgh State University of NY (PSUNY)	Todd Manning, 518–298–8240; FAX: 518–298–5538; e-mail: <a href="mailto:tmanning@ora.fda.gov">tmanning@ora.fda.gov</a>
FDA Chicago District Office, 550 West Jackson, 16th floor, Chicago, IL 60661	Darlene Bailey, 312–353–7126; FAX: 312–596–4195; e-mail: <a href="mailto:dbailey@ora.fda.gov">dbailey@ora.fda.gov</a>
Ronald V. Dellums Federal Bldg., 1301 Clay St., 3d floor, North Tower, Oakland, CA 94612	Marcia Madrigal, 510–637–3980; FAX: 510–637–3976; e-mail: <a href="mailto:mmadriga@ora.fda.gov">mmadriga@ora.fda.gov</a>
FDA/Southwest Import District, 4040 North Central Expressway, suite 300, Dallas, TX 75204	Robert Deininger, 214–253–5322; FAX: 214–253–5317; e-mail: <a href="mailto:rdeining@ora.fda.gov">rdeining@ora.fda.gov</a>
Memphis Marriot East, 2625 Thousand Oaks Dr., Memphis, TN 38118	Sandra Baxter, 615–781–5385 X122; FAX: 615–781–5383; e-mail: <a href="mailto:sbaxter@ora.fda.gov">sbaxter@ora.fda.gov</a>
FDA Detroit District Office, 300 River Pl., suite 5900, Detroit, MI 48207	Evelyn DeNike, 313–393–8109; FAX: 313–393–8139; e-mail: <a href="mailto:edenike@ora.fda.gov">edenike@ora.fda.gov</a>
Bishop Henry Whipple Federal Bldg., One Federal Dr., rm. G–110, Saint Paul, MN 55111–4008	Amy C. Johnson, 612–758–7131; FAX: 612–334–4134; e-mail: <a href="mailto:acjohnso@ora.fda.gov">acjohnso@ora.fda.gov</a>
Florida Department of Agriculture and Consumer Services (FDACS), George Eyster Auditorium, 3125 Connor Blvd., Tallahassee, FL 32399	Courtney Hunt, 850–942–8325; FAX: 850–942–8326; e-mail: <a href="mailto:chunt@ora.fda.gov">chunt@ora.fda.gov</a>
Tampa Port Authority, 1101 Channelside Dr., 1st Floor Board Room, Tampa, FL 33602	Jean Peeples, 813–228–2671 X18; FAX: 813–228–2046; e-mail: <a href="mailto:jpeeples@ora.fda.gov">jpeeples@ora.fda.gov</a>
Miami Free Zone, 2305 NW. 107th Ave., 1st Floor Conference Room, Miami, FL 33172	Estela N. Brown, 786–437–4838; FAX: 786–437–4866; e-mail: <a href="mailto:Ebrown1@ora.fda.gov">Ebrown1@ora.fda.gov</a>
FDA Atlanta District Office, 60 8th Street, NE., Atlanta, GA 30309	JoAnn Pittman, 404–253–1272; FAX: 404–253–1202; e-mail: <a href="mailto:jpittman@ora.fda.gov">jpittman@ora.fda.gov</a>
FDA Kansas City District Office, 11630 W. 80th St., Annex Conference Room, Lenexa, KS 66214	Tywanna Paul, 913–752–2141; FAX: 913–752–2111; e-mail: <a href="mailto:tpaul@ora.fda.gov">tpaul@ora.fda.gov</a>
FDA New England District Office, One Montvale Ave., Stoneham, MA 02180	Susan Small, 781–596–7779; FAX: 781–596–7896; e-mail: <a href="mailto:Ssmall@ora.fda.gov">Ssmall@ora.fda.gov</a>
FDA Kansas City District Office, 12 Sunnen Dr., suite 122, St. Louis, MO 63143	Don Aird, 314–645–1167; FAX: 314–645–2969; e-mail: <a href="mailto:daird@ora.fda.gov">daird@ora.fda.gov</a>
FDA Cincinnati District Office, 6751 Steger Dr., Cincinnati, OH 45237–3097	Bonny Carzoli, 513–679–2700 x 115.; FAX: 513–679–2771; e-mail: <a href="mailto:bcarzoli@ora.fda.gov">bcarzoli@ora.fda.gov</a>
Portland Innovative Food Center, 1207 NW. Naito Pkwy., Portland, OR 97209	Alan Bennett, 503–671–9332; FAX: 503–671–9445; e-mail: <a href="mailto:abennett@ora.fda.gov">abennett@ora.fda.gov</a>
Lake Washington Technical College, 11605 132d Ave., NE., Kirkland, WA 98034.	Stephanie Magill, 425–483–4953; FAX: 425–483–4996; e-mail: <a href="mailto:stephanie.magill@fda.gov">stephanie.magill@fda.gov</a>
Center for Food Safety and Applied Nutrition, U.S. FDA, Auditorium, 5100 Paint Branch Pkwy., College Park, MD 20740	Marion Allen, 301–436–2277, FAX: 301–436–2605, e-mail: <a href="mailto:CFSAN-FSS@cfsan.fda.gov">CFSAN-FSS@cfsan.fda.gov</a>
Texas A&M International University, WHTC Bldg., rm. 116, 5201 University, KL 262, Laredo TX 78041–1900 South Texas Community College Technology Center, 3700 West Military Hwy., McAllen, TX 78503–8807 Arizona Western College, College Union Bldg., Palo Verde Room, 2020 South Avenue 8E, Yuma, AZ 85364 PIMA Community College, 401 N. Bonita Ave., Tucson, AZ 85709 Health Services Complex, Rosecrans Bldg., 3851 Rosecrans St., San Diego, CA 92110 University of El Paso, Undergraduate Learning Center, rm. 110, 500 West University Ave., El Paso, TX 79905	Adrian Garcia, 520–281–1100, FAX: 520–281–1190, e-mail: <a href="mailto:agarcia@ora.fda.gov">agarcia@ora.fda.gov</a>
FDA/Denver District Office, Denver Federal Center, Bldg. #20, Sixth & Kipling, Lakewood, CO 80225	Virlie Walker/Devin Koontz, 303–236–3018/3020, FAX: 303–236–3551, e-mail: <a href="mailto:vwalker@ora.fda.gov">vwalker@ora.fda.gov</a> <a href="mailto:dkoontz@ora.fda.gov">dkoontz@ora.fda.gov</a>
VA Medical Center, 4th Floor Auditorium, 2202 Holcombe, Houston TX 77030	Sheryl McConnell, 713–802–7534, FAX: 713–802–7503, e-mail: <a href="mailto:smcconne@ora.fda.gov">smcconne@ora.fda.gov</a>

The sites presented in table 1 of this document are the sites scheduled to broadcast the satellite downlink as of the publication of this document.

Please check the FDA Web site at <http://www.fda.gov/oc/bioterrorism/bioact.html> for additional sites that may be added.

## V. Registration

All attendees are asked to preregister for the satellite downlink public meeting by contacting the person listed in table 1 of this document for the site you want to attend. Space is limited and registration will be closed at each site when maximum seating capacity for that site is reached. Send registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) to the contact identified in table 1 of this document at least 2 workdays before the meeting. You may register by e-mail, fax, or telephone.

If you need special accommodations due to a disability, please notify the contact person listed in table 1 of this document at least 7 days in advance of the meeting.

In addition, any interested parties with access to a satellite dish may view the downlink meetings at the following coordinates: Live simulcast in English (channel 6.8), French (channel 5.8), and Spanish (channel 6.2).

### UNITED STATES (INCLUDING ALASKA AND HAWAII) AND CANADA (C-BAND: GALAXY 3C @ 95 DEGREES WEST)

Transponder	Polarization	Channel	Downlink Freq.	Audio
3	Horizontal	3	3760 MHz	6.8 English only 6.2 Spanish 5.8 French

### MEXICO, SOUTH & CENTRAL AMERICA (C-BAND: PAS 9 @ 58 DEGREES WEST)

Transponder	Polarization	Channel	Downlink Freq.
Slot A Digital	Horizontal	24	4164.5 MHz

Video rebroadcasts will be played at several locations throughout the world. Dates and viewing times for the video rebroadcasts for Europe, Asia, Australia, South Africa, and New Zealand may be found on FDA's bioterrorism Web site at <http://www.fda.gov/oc/bioterrorism/bioact.html>. Information on

additional video rebroadcasts in English, Spanish, and French will also be available at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

## **VI. Transcripts**

Within 3 weeks of the satellite downlink public meeting, written transcripts in English, French, and Spanish will be available for viewing at DDM (see **ADDRESSES**) and posted on the following Web site: <http://www.fda.gov/oc/bioterrorism/bioact.html>. A written transcript of the satellite downlink meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, 3 weeks after the satellite downlink public meeting at a cost of 10 cents per page. A copy of the videotaped meeting may also be viewed at DDM. Or you may contact Lou Carson for a copy of the videotaped meeting and specify format and language.

Pre-event Test: A pre-event test for downlink sites will be provided on October 28 from 12 noon EST to 1 p.m. EST. During that hour, technical assistance will be available through a trouble line at 1-888-626-8730.

Dated: September 26, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**