

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket Nos. 02N–0276 and 02N–0278]

Proposed 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.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting (via satellite downlink) to discuss proposed 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. 02N–0276) and Prior Notice of Imported Food Shipments (Docket No. 02N–0278). FDA expects to publish shortly in the **Federal Register** proposed rules implementing each of these provisions. The purpose of the satellite downlink public meeting is to provide information on the proposed rules to the public and to provide the public an opportunity to ask questions or to provide comment.

DATES: Satellite Downlink Public Meeting I—Wednesday, January 29, 2003, 1 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 January 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 Dockets Management Branch (DMB) (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 DMB.

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, 301-436-2130, FAX: 301-436-2605, e-mail: Louis.Carson@cfsan.fda.gov, for general questions about the downlink, submission of advance questions, and requests for a taped 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: 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 soon will be publishing in the **Federal**

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Register notices of proposed rulemakings for each of these provisions. During the satellite downlink public meeting, FDA will explain the proposed 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 North, Central, and South America (including, Hawaii and Alaska).

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

FDA is planning a second satellite downlink meeting during which FDA will explain the proposed rules that FDA will publish shortly to implement sections 306 and 303 of the Bioterrorism Act. That meeting will be announced in a future **Federal Register** notice. FDA also plans to develop additional regulations, safety measures, and guidance documents to implement other provisions of the Bioterrorism Act. Information about the public meetings, a list of additional non-FDA Web sites for viewing the public meetings, contact information, the provisions of the Bioterrorism Act under FDA's jurisdiction, and the agency's implementation plans are available at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

Proposed rules

The proposed 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 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 final rule by October 12, 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 final rule by October 12, 2003.

A list of non-FDA parties providing other locations for viewing the downlink is provided in table 1 of this document. The parties listed are

providing this service free of charge in the interest of providing information to their constituents and to assist in creating a public process.

Table 1.—Satellite Downlink Public Meeting I—Section 305: Registration of Food Facilities and Section 307: Prior Notice of Imported Food Shipments

Date: January 29, 2003
Locations and Contact Information:
<p>Location: Advanced Training Center, 275 Oak St., Buffalo, NY 14203, 716-855-7050 Contact: Diana Monaco, U.S. FDA/Buffalo Office, 300 Pearl St., suite 100, Buffalo, NY 14202, 716-551-4461, ext. 3118, FAX: 716-551-3845, e-mail: dmonaco@ora.fda.gov</p>
<p>Location: U.S. FDA, Chicago District Office, 550 W. Jackson Blvd., 16th floor, Chicago, IL 60661, 312-596-4205 Contact: Darlene Bailey, U.S. FDA/Chicago District Office, 550 W. Jackson Blvd., Chicago, IL 60661, 312-596-4205, FAX: 312-596-4170, e-mail: dbailey@ora.fda.gov</p>
<p>Location: Lake Washington Technical School, 11605 132nd Ave. NE., rm. W-404, Kirkland, WA 98034, 425-739-8100 Contact: Sue Hutchcroft, U.S. FDA/Seattle District Office, 22201 23rd Dr., SE., Bothell, WA 98021, 425-483-4953, FAX: 425-483-4996, e-mail: shutchcr@ora.fda.gov</p>
<p>Location: VA Medical Center, 4th Floor Auditorium, 2002 Holcombe Blvd., Houston, TX 77030, 713-794-7143 Contact: Sheryl McConnell, U.S. FDA/Dallas District Office Houston Resident Post, 1445 North Loop, West, suite 420, Houston, TX 77008, 713-802-9095, ext. 115, FAX: 713-802-0906, e-mail: smcconne@ora.fda.gov</p>
<p>Location: Laredo Public Library, 1120 East Calton Rd., Laredo, TX 78041, 956-795-2400 Contact: Julio Salazar, U.S. FDA/Southwest Import District, 715 Bob Bullock Loop, rm. 75, Laredo, TX 78045, 956-729-9691, ext. 1103, FAX: 956-729-0997, e-mail: jsalazar@ora.fda.gov</p>
<p>Location: Center for Food Safety and Applied Nutrition, U.S. FDA, Auditorium, 5100 Paint Branch Pkwy., College Park, MD, 301-436-2428 Contact: Tonya Poindexter, U.S. FDA/Center for Food Safety and Applied Nutrition, rm. 3B035, College Park, MD, 301-436-1544, FAX: 301-436-1584, e-mail: tonya.poindexter@cfsan.fda.gov</p>

Registration: To register for the satellite downlink public meeting, contact the persons listed previously 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 (between 100–200 persons per site). Send registration information (including name, title, firm name, address, telephone number, e-

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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)

For the United States (including Alaska and Hawaii) and Canada

C Band

Galaxy 9 @ 127 degrees west

Ch 3 Horizontal

Downlink frequency 3740 MHz

For South and Central America

Digital

PAS 9 @ 58 west

Slot A Digital -

Ch 24 Horizontal

Downlink frequency 4160 MHz

Video rebroadcasts will be played at several locations throughout the world. Dates, and viewing times for the video rebroadcasts for Europe, Asia, Australia, New Zealand can be found on FDA's bioterrorism Web site (<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>.

Transcripts: Within 3 weeks of the satellite downlink public meeting, written transcripts in English, French, and Spanish will be available for viewing at DMB (see **ADDRESSES**) and posted on the following Web sites: <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, within 3 weeks of the satellite

downlink public meeting at a cost of 10 cents per page. Contact Lou Carson for a copy of the videotaped meeting. A copy of the video taped meeting may also be viewed at DMB.

Dated: January 3, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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

BILLING CODE 4160-01-S