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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket Nos. 02N-0275 and 02N-0277]

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 (the Bioterrorism Act) regarding maintenance and inspection of records for foods (Docket No. 02N-0277) and administrative detention (Docket No. 02N-0275). 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: The satellite downlink public meeting will be held on May 7, 2003, 1 to 3 p.m., eastern standard time. Questions submitted in advance must be received by the contact person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document by 4:30 p.m. on May 2, 2003.

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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 (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and at <http://www.fda.gov/oc/bioterrorism/bioact.html>. A copy of the videotaped meeting may also be viewed at the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Louis 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, 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:

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 Bioterrorism Act (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). On February 3, 2003, FDA published in the **Federal Register** notices of proposed rulemaking for registration of food facilities (68 FR 5378) and prior notice of imported food shipments (68 FR 5428), and will soon publish in the **Federal Register** notices of proposed rulemaking for maintenance and inspection of records for foods and administrative detention. During the satellite downlink public meeting, FDA will explain the proposed rules on maintenance and inspection of records for foods and administrative detention and will answer questions. The satellite downlink public meeting will be offered in English with simultaneous French and Spanish translation and will be simulcast live in English, French, and Spanish for North, Central, and South America (including Hawaii and Alaska).

On January 29, 2003, FDA held a satellite downlink meeting during which FDA explained the proposed rules for registration of food facilities and prior notice of imported food shipments to implement sections 305 and 307 of the Bioterrorism Act, respectively. You may download a copy of the videotape of this meeting at <http://www.cfsan.fda.gov/~comm/vltbtact.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 Louis Carson for a copy of the videotaped meeting. A copy of the video taped meeting may also be viewed at the Dockets Management Branch.

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>.

II. Submitting Questions

Interested persons may submit questions concerning the proposals in advance of the satellite 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 during the downlink meeting. The viewing audience may also telephone, fax, or e-mail questions to FDA officials during the live downlink.

III. Proposed Regulations to be Addressed

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 303 (Administrative Detention) of the Bioterrorism Act authorizes FDA to detain food if the agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. The Bioterrorism Act requires FDA to issue regulations to provide procedures for instituting on an expedited basis certain enforcement actions against perishable foods, but it does not specify a deadline for a final regulation.

Section 306 (Maintenance and Inspection of Records for Foods) of the Bioterrorism Act authorizes FDA, by regulation, to require persons that manufacture, process, pack, transport, distribute, receive, hold, or import food to create and maintain records that FDA determines are necessary to identify

the immediate previous sources and the immediate subsequent recipients of food (i.e., where it came from and who received it). This would allow FDA to follow up on credible threats of serious adverse health consequences or death to humans or animals by tracing the food back to its source and tracing the food forward to all recipients. Farms and restaurants are exempt from any recordkeeping regulations that are issued by FDA. The statute requires FDA to issue final regulations by December 12, 2003.

IV. Sites for Viewing the Downlink Public Meeting

A list of non-FDA parties providing other locations for viewing the downlink public meeting 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.—MAY 7, 2003, SATELLITE DOWNLINK PUBLIC MEETING TO DISCUSS PROPOSED REGULATIONS IMPLEMENTING SECTION 303: ADMINISTRATIVE DETENTION AND SECTION 306: MAINTENANCE AND INSPECTION OF RECORDS FOR FOODS OF THE BIOTERRORISM ACT

Locations	Contact Information
Department of Veterans Affairs Medical Center, Pete Wheeler Auditorium, 1670 Clairmont Rd., Decatur, GA 30033, 404-321-6111, ext. 6050.	JoAnn Pittman, U.S. FDA/Atlanta District Office, 60 8th St., NE., Atlanta, GA 30309, 404-253-1272, FAX: 404-253-1202, email: jpittman@ora.fda.gov.
U.S. FDA, Detroit District Office, 300 River Pl., suite 5900, Detroit, MI 48207-4291, 313-393-8109.	Evelyn DeNike, U.S. FDA/Detroit District Office, 300 River Pl., suite 5900, Detroit, MI 48207-4291, 313-393-8109, FAX: 313-393-8139, email: edenike@ora.fda.gov.
Massachusetts Department of Public Health, Division of Food and Drugs, 305 South St., Jamaica Plain, MA 02130, 617-983-6767.	Susan Small, U.S. FDA/New England District Office, One Montvale Ave., Stoneham, MA 02180, 781-596-7779, FAX: 781-596-7896, email: ssmall@ora.fda.gov.
University of California Irvine, C-127 Student Center (at E. Peltason/Periera), Emerald Bay B and C, Irvine, CA 92697.	Ramlah I. Oma, U.S. FDA/Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612-2445, 949-798-7611, FAX: 949-798-7656, email: roma@ora.fda.gov.
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 20740, 301-436-2277, FAX: 301-436-2605, email: CFSAN-FSS@cfsan.fda.gov.

In addition, any interested parties with access to a satellite dish may view the downlink meeting at the following coordinates:

Live simulcast in English (channel 6.8), French (channel 5.8), and Spanish (channel 6.2).

Pre-event Test: A pre-event test for U.S. downlink sites only will be provided on May 6 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." This is a test of Galaxy 9, Transponder 3 only.

U.S.—C-Band: Galaxy 9 127 degrees West

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

Mexico & South America—C-Band: PAS 9 58 degrees West

Transponder	Polarization	Channel	Digital Settings	Downlink Freq.	Audio
24 Slot C - Digital	Horizontal	24	4:2:0 FEC 3/4 Symbol Rate: 5.632	4164.5 MHz	6.8 English 6.2 Spanish 5.8 French

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>.

Videostream copies of the satellite downlink meeting will be available in English, Spanish, and French on CD-ROM within 10 working days after the meeting. Copies of the meeting will also be available on videotape cassettes in English, Spanish, and French in NTSC (VHS), PAL, PAL-N and SECAM formats. Contact Louis Carson for a copy of the meeting on CD-ROM or videotape. Videotape requests must specify language and format. A videostream of the meeting will be posted on FDA's Web site at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

V. Registration

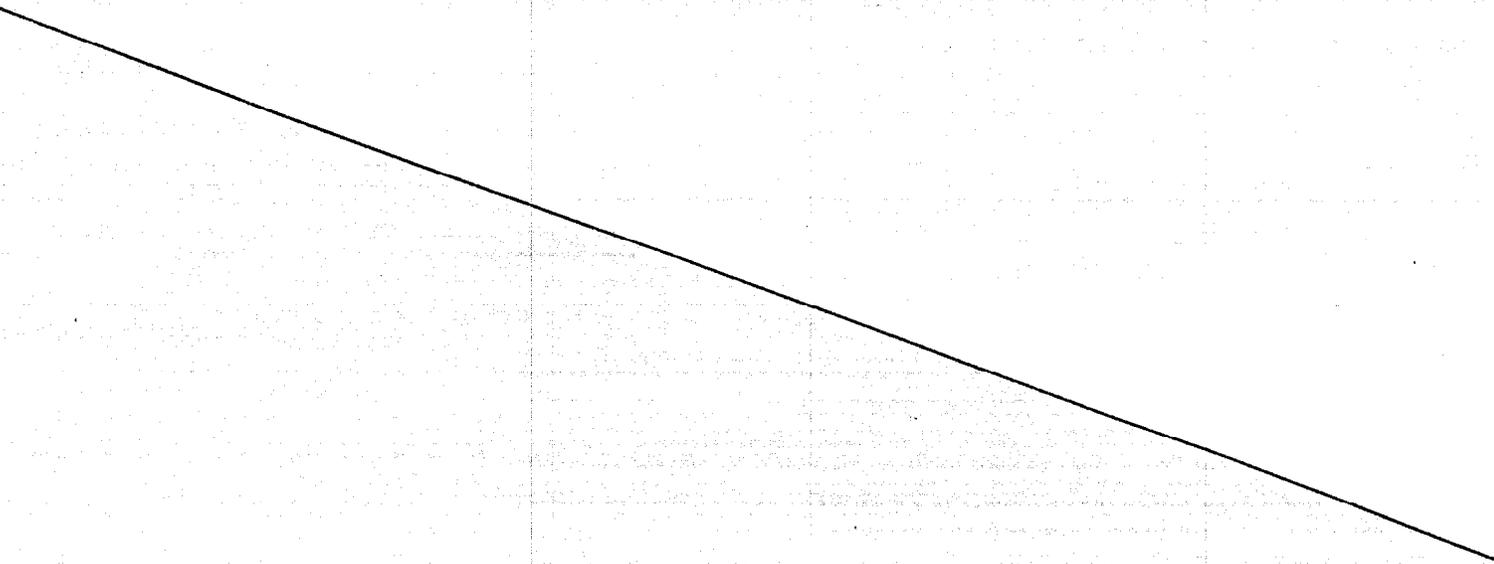
To register for the satellite downlink public meeting, contact the persons listed in table 1 in this document for the site you want to attend. Space is limited and registration will be closed at each site once maximum seating

capacity for that site is reached (between 100 and 200 people per site). Send registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) for each attendee to the contact identified in table 1 of this document no later than May 5, 2003. 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.

VI. Transcripts

Within 3 weeks of the satellite downlink public meeting, written transcripts in English, French, and Spanish will be available for viewing at the Dockets Management Branch (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, within 3 weeks of the satellite downlink public meeting at a cost of 10 cents per page. Contact Louis Carson for a copy of the videotaped meeting. A copy of the video taped meeting may also be viewed at the Dockets Management Branch.



Dated: 4/2/03
April 2, 2003.

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Jeffrey Shuren,
Assistant Commissioner for Policy.

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