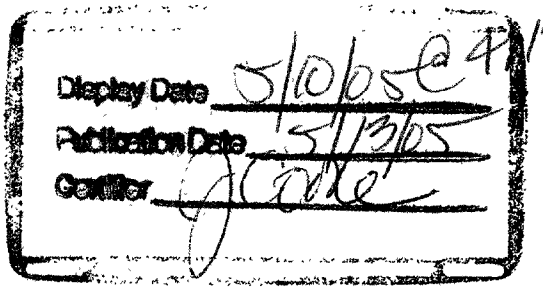
DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–0277] (formerly 02N–0277)

Final Regulation Implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—Establishment and Maintenance of Records for Foods; Notice of Public Meetings

AGENCY: Food and Drug Administration, HHS.

REVISIONS

ACTION: Notice of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of domestic public meetings to discuss the final regulation implementing section 306 (Maintenance and Inspection of Records) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The purpose of these public meetings is to provide to the public information and an opportunity to ask questions regarding the final rule.

DATES

~~*Dates and Times*~~: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document for meeting dates and times.

ADDRESSES

~~*Locations*~~: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document for meeting locations.

FOR FURTHER INFORMATION CONTACT

~~*Contact*~~: *For general questions about the meeting*: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1601, FAX: 301 436 2605, e-mail: *marion.allen@fda.hhs.gov*

Please see III. **Registration for the Public Meetings** for information on how to register for specific site locations.

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.

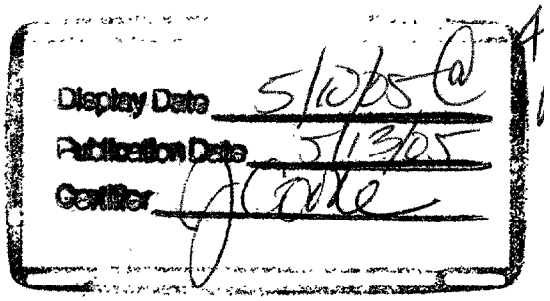
FDA published in the **Federal Register** of December 9, 2004 (69 FR 71562), the final rule implementing section 306 of the Bioterrorism Act and a notice of availability for a draft guidance on records access under the Bioterrorism Act (69 FR 71657). During the public meetings, FDA will explain the final rule and draft guidance, and answer questions for clarification.

II. Final Rule and Draft Guidance

Section 306 of the Bioterrorism Act directs the Secretary of Health and Human Services (the Secretary) to issue final regulations that establish requirements regarding the establishment and maintenance, for not longer than 2 years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. The records required by these regulations are those that are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The regulation implements the recordkeeping authority in the Bioterrorism Act.

DMD

DEPARTMENT OF HEALTH AND HUMAN SERVICES



Food and Drug Administration

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SUPPLEMENTARY INFORMATION:

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In addition, the Bioterrorism Act provides records inspection authority to FDA such that if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records. FDA will also discuss the draft guidance for records access authority provided for in the Bioterrorism Act, explaining how we will implement access authority.

III. Registration for the Public Meetings

Please submit your registration information (including name, title, firm name, address, telephone number, e-mail address, and fax number) at least 5 workdays before the public meeting date. For specific site locations, we encourage you to register online at *http://www.cfsan.fda.gov/dms/fsbtac26.html* or to fax your registration directly to Isabelle Howes at 202–479–6801. We will accept registrations onsite. Space is limited and registration will be closed at each site when maximum seating capacity for that site is reached (300 persons per site location).

If you need special accommodations due to a disability, please notify the contact person listed under *Contact* in this document at least 7 workdays in advance of the meeting.

All participants must present a valid photo identification when entering a Federal building and parking facility.

IV. Dates, Times, and Addresses of Public Meetings

TABLE 1.—PUBLIC MEETINGS—SECTION 306: ESTABLISHMENT AND MAINTENANCE OF RECORDS FOR FOODS

Date and Time	Location
Tuesday, June 7, 2005, 9 a.m. to 1 p.m., c.s.t.	Marriott, 775 Brasilia Ave., Kansas City, MO 64153, 816–464–2200
Wednesday, June 8, 2005, 9 a.m. to 1 p.m., P.s.t.	Los Angeles Airport Marriott, 5855 West Century Blvd., Los Angeles, CA 90045, 310–641–5700
Thursday, June 9, 2005, 9 a.m. to 1 p.m., e.s.t.	Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD 20740
Tuesday, June 14, 2005, 9 a.m. to 1 p.m., c.s.t.	Embassy Suites at Minneapolis Airport, 7901 34th Ave., Bloomington, MN 55425, 952–854–1000

TABLE 1.—PUBLIC MEETINGS—SECTION 306: ESTABLISHMENT AND MAINTENANCE OF RECORDS FOR FOODS—Continued

Date and Time	Location
Wednesday, June 15, 2005, 9 a.m. to 1 p.m., e.s.t.	Atlanta, GA, Renaissance Waverly, 2450 Galleria Pkwy., Atlanta, GA 30339, 770–953–4500

V. Transcripts

A transcript will be made of the proceedings of each meeting. You may request a copy of a meeting transcript in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the public meetings at a cost of 10 cents per page. The transcript of each public meeting will be available for public examination at the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Information about the public meetings, contact information, and the provisions of the Bioterrorism Act under FDA's jurisdiction can be accessed at *http://www.fda.gov/oc/bioterrorism/bioact.html* and *http://www.cfsan.fda.gov/dms/fsbtact.html.*

Dated: MAY - 9 2005

May 9, 2005

Jeffrey Shuren

Jeffrey Shuren
Assistant Commissioner for Policy

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S