§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(c) to establish, maintain, or establish and maintain, records required under § 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2004, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (f) to read as follows:

§ 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: November 30, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

Dated: December 2, 2004.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 04–26929 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2002N–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 Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; public meeting on final rule.

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), which is publishing in this issue of **Federal Register**. The purpose of these public meetings is to provide information on the rule to the public and to provide the public an opportunity to ask questions of clarification.

DATES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Marion V. Allen, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1584, FAX: 301–436–2605, e-mail: *marion.allen@fda.hhs.gov*, for general questions only about the meeting.

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.

In this issue of the **Federal Register**, FDA is publishing the final rule implementing section 306 of the Bioterrorism Act and a draft guidance on records access under the Bioterrorism Act. During the public meetings, FDA will explain this rule and the draft guidance and answer questions of clarification.

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*.

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 that must be kept 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. This regulation implements the recordkeeping authority in the Bioterrorism Act.

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, and the records are necessary to assist FDA in making such a determination, persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food must provide access to records.

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 working days before the public meeting date. For specific site locations, we encourage you to register online at *http://www.cfsan.fda.gov/~dms/fsbtac23.html* or fax directly to Sharon Barcellos at 202–479–4970. We will accept registration onsite. Space is limited and registration will be closed at each site when maximum seating capacity for that site is reached (between 100 to 200 persons per site). If you need special accommodations due to a disability, please notify the contact person as listed under **FOR FURTHER INFORMATION CONTACT** in this document at least 7 working days in advance of the meeting. All participants must present valid photo identification when entering a Federal building and parking facility.

IV. Dates, Times, and Addresses of Public Meetings

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

DATES	LOCATION
Thursday, January 13, 2005	Harvey W. Wiley Federal Bldg. 5100 Paint Branch Pkwy. College Park, MD 20740 Time: 9 a.m. to 1 p.m. EST
Tuesday, January 25, 2005	Courtyard by Marriott Chicago 165 E. Ontario St. Chicago, IL 60611 312–573–0800 Time: 9 a.m. to 1 p.m. CST Renaissance Seattle Hotel 515 Madison St. Seattle, WA 98104 800–546–9184 Time: 9 a.m. to 1 p.m. PST
Thursday, January 27, 2005	San Francisco Downtown Courtyard 299 Second St. San Francisco, CA 94105 415–947–0700 Time: 9 a.m. to 1 p.m. PST Wyndham Orlando Resort 8001 International Dr. Orlando, FL 32819 407–351–2420 Time: 9 a.m. to 1 p.m. EST
Tuesday, February 1,2005	Renaissance Philadelphia Airport Hotel 500 Stevens Dr. Philadelphia, PA 19113 610–521–5900 Time: 1 p.m. to 5 p.m. Hilton Boston Back Bay 40 Dalton St. Boston, MA 02115 617–236–1100 Time: 9 a.m. to 1 p.m.

IV. 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.

Dated: December 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26930 Filed 12–6–04; 8:45 am]

BILLING CODE 4160–01–S