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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.

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

ADDRESSES: See table 1 of the SUPPLEMENTARY INFORMATION section of this document for meeting locations.

FOR FURTHER INFORMATION 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, 301-436-1584, 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2004 (69 FR 71562), the final rule implementing section 306 of the Bioterrorism Act and a notice of availability for a draft guidance on records access under the Bioterrorism Act (69 FR 71657). During the public meetings, FDA will explain the final rule and draft guidance, and answer questions for clarification.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 Final Rule and Draft Guidance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.

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
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.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-9536 Filed 5-10-05; 4:13 pm]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, and 1307

[Docket No. DEA-240F]

RIN 1117-AA75

Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to allow, where State laws permit, for retail pharmacy installation of automated dispensing systems at long term care facilities. Automated dispensing systems would allow dispensing of single dosage units and mitigate the problem of excess stocks and disposal.

DATES: *Effective Date:* This final rule is effective June 13, 2005.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

I. Background

Legal Authority

DEA enforces the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*), as amended. DEA regulations implementing this statute are published in Title 21 of the Code of Federal Regulations (CFR), part 1300 to 1399. These regulations are designed to establish a framework for the legal distribution of controlled substances to deter their diversion to illegal purposes and to ensure that there is a sufficient supply of these drugs for legitimate medical purposes. Controlled substances are those substances listed in the schedules of the CSA and 21 CFR 1308.11-1308.15, and generally include narcotics, stimulants, depressants, hallucinogens, and anabolic steroids that have a high potential for abuse and dependency. DEA's regulations require that persons involved in the manufacture, distribution, research, dispensing, import, and export of controlled substances register with DEA, keep track of all stocks of controlled substances, and maintain records to account for all controlled substances received, distributed, or otherwise disposed of.

Controlled Substances at Long Term Care Facilities (LTCFs)

DEA defines a long term care facility as "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients" (21 CFR 1300.01(b)(25)). Patients at LTCFs take numerous medications, including controlled substances. Unlike hospitals, LTCFs are rarely DEA registrants, (although DEA regulations do allow an LTCF to register if licensed by its State to handle controlled substances). Patients at these facilities are usually seen by their personal physicians, who prescribe any necessary medication. These prescriptions are filled by retail pharmacies and delivered to the LTCFs for patients' use. Because LTCFs usually are not registrants and generally do not have physicians or pharmacists on staff, they may not order and maintain stocks of controlled substances to be dispensed under the order of a practitioner as occurs in hospitals. Instead, the controlled substance medications are dispensed under a prescription to the specific patients by a provider pharmacy; the LTCF holds the drugs in a custodial manner for administration to the patient. DEA permits pharmacies to dispense a Schedule II prescription for a LTCF patient on a daily or dosage unit

basis rather than dispense the entire quantity prescribed. Reimbursement rules under Medicare and Medicaid and other third party payers, however, make daily dispensing financially unattractive for pharmacies; pharmacies are allowed a limited number of dispensing fees plus the calculated cost of the medication per month. Consequently, pharmacies routinely dispense the entire prescription to the patient at once; the LTCF maintains the drugs and ensures that they are taken as prescribed.

A result of this dispensing practice is that when patients leave the facility or their medications change, the LTCF may be left with excess controlled substances, which must be disposed of to avoid diversion. Because they are not registrants, the LTCFs may not transfer the substances to either the pharmacy that supplied them or to a reverse distributor for disposal. The LTCF must dispose of the excess controlled substances directly.

DEA's Proposal

To address the issue of excess controlled substances in LTCFs, DEA issued a Notice of Proposed Rulemaking (NPRM) (68 FR 62255; November 3, 2003) proposing to allow a provider pharmacy to register at the site of the LTCF and store controlled substances in an automated dispensing system (ADS). An ADS is conceptually similar to a vending machine. A pharmacy stores bulk drugs in the machine in separate bins or containers and programs and controls the ADS remotely. Only authorized staff at the LTCF would have access to its contents, which are dispensed on a single-dose basis at the time of administration under a prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. If patients do not take all of the drugs prescribed, the excess can be dispensed to other patients.

DEA's proposal allowed the use of automated dispensing systems as an option, not a requirement. DEA recognizes that there are reasons why ADSs may not work in many circumstances, but believes that some LTCFs will find ADSs a viable solution for preventing accumulation of excess controlled substances.

Current Federal law does not prohibit the use of ADSs for storage and dispensing of controlled substances at LTCFs where the LTCF itself is a DEA registrant. However, to allow the use of