

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Parts 1 and 11

[Docket No. 02N-0277]

RIN 0910-AC39

### Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing regulations that would require the establishment and maintenance of records by certain domestic persons who manufacture, process, pack, transport, distribute, receive, hold, or import food intended for human and animal consumption in the United States. In addition, these requirements apply to certain foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The proposed regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and are necessary to properly address credible threats of serious adverse health consequences or death to humans and animals. FDA expects that the requirements the agency is proposing in these regulations, if finalized as proposed, would result in a significant improvement in FDA's ability to respond to and help contain threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

**DATES:** Submit written or electronic comments by July 8, 2003. Written comments on the information collection provisions should be submitted by June 9, 2003.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including

first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov) or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202-395-6974.

#### FOR FURTHER INFORMATION CONTACT:

Nega Beru, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1400.

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#### I. Background and Legal Authority

##### *A. Public Health Security and Bioterrorism Preparedness and Response Act of 2002*

The events of September 11, 2001, reinforced 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 ("the Bioterrorism Act") (Public Law 107-188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A—Protection of Food Supply, section 306 (21 U.S.C. 335a), which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 414, Maintenance and Inspection of Records (21 U.S.C. 350(c)). Section 414(b) of the act provides, in part, that the Secretary of Health and Human Services (the Secretary), may by regulation 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. In section 306(d) of the Bioterrorism Act, Congress directed the Secretary to issue proposed and final regulations establishing recordkeeping requirements under section 414(b) of the act no later than 18 months after enactment of the Bioterrorism Act, that is, by December 12, 2003.

In addition, the Bioterrorism Act adds a new section 414(a) to the act that