SUPPORTING STATEMENT

RECORDKEEPING AND RECORDS ACCESS REQUIREMENTS FOR FOOD FACILITIES

OMB No. 0910-0560

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) added section 414 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350c), which requires that persons who manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Sections 1.326 through 1.363 (21 CFR 1.326 through 1.363) of FDA's regulations set forth the requirements for recordkeeping and records access. The requirement to establish and maintain records improves FDA's ability to respond to, and further contain, threats of serious adverse health consequences or death to humans or animals from accidental or deliberate contamination of food.

We request the extension of OMB approval for the following collection of information requirements:

21 CFR 1.337 -- Recordkeeping

Requires respondents to establish and maintain records to identify the immediate previous sources of food.

21 CFR 1.345 -- Recordkeeping

Requires respondents to establish and maintain records to identify the immediate subsequent recipients of food.

21 CFR 1.352 -- Recordkeeping

Requires respondents to establish and maintain records for each food they transport in the United States.

2. Purpose and Use of the Information Collection

Information maintained under these regulations will help FDA to identify and locate quickly food that might be affected by deliberate or accidental contamination and to inform the appropriate individuals and food facilities of specific terrorist threats. FDA's regulations require that records for non-transporters include the name and full contact information of sources, recipients, and transporters, an adequate description of the food including the quantity and packaging, and the receipt and shipping dates (§§ 1.337 and 1.345). Required records for transporters include the

names of consignor and consignee, points of origin and destination, date of shipment, number of packages, description of freight, route of movement and name of each carrier participating in the transportation, and transfer points through which shipment moved (§ 1.352). Existing records may be used if they contain all of the required information and are retained for the required time period.

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies may opt to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials.

4. Efforts to Identify Duplication and Use of Similar Information

To the best of our knowledge, no other federal government agency is engaged in the collection of this information. There can be no duplicative collection of this information because the information maintained in fulfilling the statutory requirements for recordkeeping under section 414 of the act is unique to each firm and its customers and suppliers. Moreover, the regulation states that,

> The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released. (21 CFR 1.330)

5. Impact on Small Businesses or Other Small Entities

The recordkeeping requirements of these regulations are mandated by section 414 of the act and there is no statutory exception for small businesses. However, FDA staggered the dates by which very small, small, and large sized firms were required to comply with the rule. Very small firms were given 24 months to comply, small firms were given 18 months, while large firms were given 12 months In addition, FDA has Small Business Representatives who help small businesses whose products are regulated by FDA.

6. Consequences of Collecting the Information Less Frequently

Pursuant to the act and the implementing regulations, a record is established for each transaction involving food at the time the transaction occurs. The information cannot be collected less frequently. If the collection is not conducted or is conducted less frequently, persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States would not be in compliance with section 414 of the act. If the required records are not maintained, FDA may not be able to identify and locate quickly food that might be affected by deliberate or

accidental contamination or to inform the appropriate individuals and food facilities of specific terrorist threats.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The recordkeeping regulations that are the basis for this collection of information generally do not require submission of information to FDA. FDA may inspect the records by invoking the access provisions of § 1.361, which require that FDA have "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." Thus, this collection of information does not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information. The collection fully complies with 5 CFR 1320.5(d)(2).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of November 19, 2007 (72 FR 65033), FDA published a 60-day notice requesting public comment on the information collection provisions. We received no comments.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The regulation does not specify confidentiality. However, all confidential information received by FDA is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]					
21 CFR Section	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	18,975	1	18,975	4.790	90,890
Total					5,110,890

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's estimate of the number of facilities affected by the final rule entitled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," published in the Federal Register of December 9, 2004 (69 FR 71562 at 71630). With regard to records maintenance, FDA estimates that approximately 379,493 facilities will spend 13.228 hours collecting, recording, and checking for accuracy of the limited amount of additional information required by the regulations, for a total of 5,020,000 hours annually. In addition, FDA estimates that new firms entering the affected businesses will incur a burden from learning the regulatory requirements and understanding the records required for compliance. In this regard, the agency estimates the number of new firms entering the affected businesses to be five percent (5%) of 379,493, or 18,975 firms. Thus, FDA estimates that approximately 18,975 facilities will spend 4.790 hours learning about the recordkeeping and records access requirements, for a total of 90,890 hours annually. Therefore, the total annual recordkeeping burden is estimated to be 5,110,890 hours.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the average hourly wage of the recordkeepers is $15 per hour. The overall estimated cost incurred is $76,663,350 (5,110,890 burden hours X $15/hr = $76,663,350).

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to Federal Government

There are no annual costs to the Federal government associated with this collection of information.

15. Explanation for Program Changes or Adjustments

The decrease of 248,110 burden hours is due primarily to a reduction in the estimated hours per record.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

FDA has not identified any exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I.