Recordkeeping and Records Access Requirements for Food Facilities

Supporting Statement

A Justification

1. Circumstances Necessitating Information Collection

The Bioterrorism Act contains a provision authorizing the Secretary to establish requirements regarding the establishment and maintenance of records by persons who manufacture, process, pack, hold, receive, distribute, transport, or import food to maintain records identifying the immediate previous sources and immediate subsequent recipients of food, animal food, or food ingredients. Records for non-transporters must 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. 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.

The United States has been victim to numerous attacks from terrorist and members of the public. Although, most of these attacks have been attacks directed at buildings or other structures, the United States food supply is also at risk from deliberate attacks. This regulation will enable the FDA to respond to, and help contain, adulterated food that presents a threat of serious adverse health consequences or death to humans or animals by

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addressing shortfalls in current recordkeeping practices. These shortfalls inhibit current outbreak investigation efforts and, by extension, efforts to mitigate serious adverse health consequences or death to humans or animals. The perceived vulnerability of the U.S. food supply to an attack, as articulated by Congressional passage of the Bioterrorism Act, elevates the importance of addressing these shortfalls. An example of an intentional food contamination that serves to highlight some vulnerabilities addressed by this rule includes the contamination of restaurant salad bars by members of the Rahneeshpuram commune in The Dalles, Oregon in an attempt to influence a local election. This attack sickened at least 751 people and sent 45 people to the hospital. Deliberate contamination was not immediately suspected and a year passed before law enforcement brought charges against the terrorists. The threat for further food-based attacks exists.

2. How, By Whom, Purpose of Collection

Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food are required to maintain records, including facilities in both interstate and intrastate commerce.

Records for non-transporters must 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. Records for transporters must include similar information about the food or food packaging, sources, and recipients, identification of all modes of transportation, and responsible individuals, while the food or food packaging is in the custody of the transporter.

Data collected as a result of the recordkeeping and records access requirements will be used to aid FDA in their investigative and enforcement activities and to inform the appropriate individuals and food facilities of specific terrorist threats.

3. Use of technology to reduce the burden on the public.

Because the rule is in the form of a performance requirement, facilities are encouraged to maintain electronic records to the extent that it facilitates and expedites their access if needed.

4. Identification and Use of Duplicate Information

The information required by this rule is not now required elsewhere by the FDA. Since the recordkeeping requirements are based on a performance standard, respondents may not have to collect any additional information if it is all ready being collected and is reasonably accessible.

5. FDA's Efforts to Reduce Burden on Small Business

FDA will stagger the dates by which very small, small, and large sized firms need to comply with the rule. Very small firms are given 24 months before they need to comply, small firms are given 18 months, while large firms are given 12 months for compliance. This will significantly reduce the burden on very small firms compared to large firms.6. Impact of Not Collecting This Information or Collecting Information Less Frequently

If the required information is not collected on a continued basis, the capacity of the FDA to respond to a known or potential threat to the food supply or other food-related emergencies may be reduced.

7. Explain any special circumstances that occur when collecting the information

No special circumstances.

8. Identification of Outside FDA Sources

FDA already has held many meetings with embassies, and national and international organizations. In addition, FDA received and addressed over 210 public comments to the proposal from industry associations, consumer groups, and other national and international sources. The following are comments that pertain to the information collection.

Comment) One commenter states that the cumulative effect of the regulation is a staggering amount of required paperwork that needs to be organized and made available.

(Response) This comment is not directly responding to any specific request for comments but is a general comment. The duplication of records is unnecessary as long as existing records contain all of the required information. In the PRIA, FDA estimated the impacts of the costs of compliance on small businesses using FDA's small business model (Ref. 1). The estimated one-time compliance costs for the high estimate of costs in the second year of compliance were used in the model to compute the number of businesses that would incur negative cash flows. As an example of the results, 0.1 percent of firms with fewer than 20 employees in the candy industry and no firms in the

ready-to-eat food sector would incur higher pre-tax costs than revenues. When the much lower recurring annual compliance costs are used in the computation, there are no businesses that would incur negative cash flows. Therefore, based on the results from the above referenced model, there are likely to be no firms that would go out of business as a result of this regulation.

(Comment) One commenter states that the PRA was adopted to prevent the burden of collecting unnecessary information that has little practical utility or benefit. The commenter further states that FDA needs to realign the benefits with the costs of the regulation.

(Response) This is a response to the request for comments on whether the information required in the proposal would have any practical utility. Compared to the description of the costs in the proposal, the benefits were not as well defined. In the final rule, the benefits of each provision are more clearly identified, which facilitates greater realignment of costs with the benefits of the regulation.

(Comment) One commenter suggests that FDA should reduce the paperwork burden by integrating the paperwork requirements from this regulation with current Customs process so that only one form needs to be completed.

(Response) The final recordkeeping regulation excludes all foreign persons, except for foreign persons who transport food in the United States so that many foreign persons do not have to establish or maintain records. Moreover, neither the proposed nor final rules specify the form or format of required records. Accordingly, existing records used for Customs' purposes may be used if they contain all of the information required by this rule and are retained for the required time period.

9. Payment of Gifts Offered to Respondents

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

10. Confidentiality Provisions

The information collected will be used only to help ensure the safety of the United States food supply. The information collected may be requested by the FDA only if it would be useful to respond to a known or potential threat to the food supply or other food-related emergency.

11. Use of Sensitive Questions

There are no questions that would be considered sensitive.

12. and 13. Burden Hours and Annual and Total Costs Associated With This Information Collection

Burden: FDA estimates that the paperwork burden of this final rule will be incurred by approximately 707,672 facilities owned by 581,943 firms. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food as well as foreign persons who transport food in the United States. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 of this final rule includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the registration interim final rule (68 FR 58894, October 10, 2003). The learning burden presented in table 1 of this

document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following issuance of the final rule.

The records redesign burden presented in table 1 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the final rule. The burden from this activity is reported in table 1of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 2 of this document.

Table 1: Estimated Annual Recordkeeping Burden--First and Second Years[1]

21 CFR Section	Number of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352 (learning)	707,672	1	707,672	4.790		3,390,000
1.337, 1.345, and 1.352 (redesign)	150,358	1	150,358	29.084	$70,409,000	4,373,000
Total						7,763,000

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

Table 2: Estimated Annual Recordkeeping Burden--Subsequent Years[1]					
21 CFR Section	Number of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (additional records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	70,767	1	70,767	4.790	339,000
Total					5,359,000

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

14. Annual Cost to Government

There are no annual costs to the government.

15. Reason for Change

This is a new collection requirement.

16. Statistical Reporting

FDA has no plans for publication from this information collection.

17. Display of OMB Approval Date

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", of OMB Form 83I.

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