INFANT FORMULA RECALL REGULATIONS

OMB No. 0910-0188

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations in part 107 (21 CFR part 107) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

We request OMB approval for the following information collection requirements contained in part 107:

21 CFR 107.230 – Reporting

Requires each recalling firm to evaluate the hazard to human health, devise a written recall strategy, promptly notify each affected direct account (customer) about the recall, and furnish the appropriate FDA district office with copies of these documents.

If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice.

21 CFR 107.240 - Reporting

Requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated.

21 CFR 107.250 - Reporting

Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence.

21 CFR 107.260 - Disclosure - Notification

Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications.

21 CFR 107.280 - Recordkeeping

Requires the recalling firm to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula, to facilitate location of the product being recalled.

2. Purpose and Use of the Information Collection

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

3. Use of Improved Information Technology and Burden Reduction

FDA has emphasized to manufacturers the importance of coding each lot of formula produced and retaining the shipping and distribution records for each lot. The coding identifies the location and date of manufacture, and what line within the plant that produced the problem product. When it becomes necessary to recall a product, this information allows the manufacturer to locate the exact point in the manufacturing process or the distribution chain

where the problem occurred. This automated system handles the recordkeeping routinely, allows for the orderly return of the problem product to the manufacturer, and results in significant savings in time and money in the event a recall is necessary.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency that collects this information. No duplication can occur as each manufacturer is responsible for his own shipping routes and records. Each recall of an infant formula product is unique. The information needed to accomplish the recall is the exact shipping and distribution pattern for a specific lot or group of lots of a particular product. The information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

The production of processed foods requires that producers take on a very high degree of responsibility, especially for infant formula products. In the event of a recall, the safety of infants is involved and the first priority is the removal of hazardous foods (infant formulas) from channels of commerce. FDA will provide assistance to any firm in achieving this goal. Also, FDA aids small businesses in dealing with the requirements through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the Agency.

6. Consequences of Collecting the Information Less Frequently

A recall is the result of a realization that an adulterated or misbranded infant formula which presents a risk to human health is present in the marketplace. The frequency of such recalls cannot be predicted. If manufacturers were more reluctant to conduct recalls, FDA, in order to protect the public health, would be required to initiate seizure action or another type of regulatory action to remove these products from channels of commerce.

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

Respondents are required to report more often than quarterly and to prepare a written response in less than 30 days. In the event of a recall, § 107.240 requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated. This early notification allows the agency the opportunity to evaluate and comment on the recalling firm's strategy. In addition, such notification eliminates needless regulatory actions which the agency might otherwise take against violative products in order to protect the public health. For example, FDA would not normally initiate a seizure action against a violative infant formula if it knew that the shipment was being recalled by the responsible firm. Frequent reporting is required to protect the health of the infant consumer because these products are used as the sole source of sustenance for this highly vulnerable population group.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of March 26, 2008 (73 FR 16018). No comments were received.

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

FDA provides no assurance of confidentiality to firms that voluntarily decide to, or are required to, conduct recalls.

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

Respondents to this collection of information are manufacturers of infant formula.

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	2	1	2	4,500	9,000
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260	1	1	1	650	650
Total					12,854

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

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been, on average, two infant formula recalls per year for the past 3 years. Thus, FDA estimates that two respondents will conduct recalls annually pursuant to §§ 107.230, 107.240, and 107.250. The estimated number of respondents for § 107.260 is minimal because this section is seldom used by FDA; therefore, the agency estimates that there will be one or fewer respondents annually for § 107.260. The estimated number of hours per response is an average based on the agency's experience and information from firms that have conducted recalls.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

Estimated Annualized Cost for the Burden Hours:
FDA estimates the annualized cost to respondents for the hour burden associated with the requirements of this regulation to be approximately $664,166. This estimate is based upon an industry employee making a salary equivalent to a GS-14 step 4 level in the locality pay area of Washington-Baltimore at $51.67/hour in 2008 ($51.67/hr x 12,854 hrs = $664,166.18).

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.

14. Annualized Cost to Federal Government

The estimated cost to the Federal Government to respond to the current level of infant formula recalls is approximately $273,777. This is based on the salaries of five (5) FTE's at an average salary of GS-13, Step 4, in the Washington-Baltimore Locality Pay Area for 2008 ($91,259/year) who each spend an estimated 3/10 of their time on infant formula recalls (5 FTE x $91,259/yr x 0.3

= $136,888.5). To account for overhead, this cost is increased by 100 percent, making the estimated cost to the Federal Government $273,777.

15. Explanation for Program Changes or Adjustments

The estimate of the number of burden hours is unchanged. At this time the agency does not have any reason to expect the number of recalls to change over the next three years.

16. Plans for Tabulation and Publication and Project Time Schedule

Once a recall of infant formula has been determined to be necessary, the firm is required to notify each of its affected accounts of the recall, and instruct each consignee to report whether or not they are in possession of the recalled infant formula and include a means to do so. If necessary a public warning is to be given.

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

We are not seeking approval to not display the expiration date for OMB approval of this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.