SUPPORTING STATEMENT

INFANT FORMULA REQUIREMENTS

OMB No. 0910-0256

A. JUSTIFICATION

1. Need and Legal Basis

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the act) are intended to protect the health of infants and include a number of reporting and recordkeeping requirements. Among other things, section 412 of the act (21 U.S.C. 350a) (Attachment A), which was added by the Infant Formula Act of 1980 (IFA), requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. FDA has issued regulations to implement the act's requirements for infant formula in 21 CFR part 106 and part 107 (21 CFR parts 106 and 107) (Attachment B). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343) (Attachment C). Under the labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

Exempt infant formulas are defined as any infant formula which is represented or labeled for use by an infant who has an inborn error of metabolism or a low birth weight, or who otherwise has an unusual medical or dietary problem. Section 412(h)(1) of the act authorizes the Secretary to establish terms and conditions for the exemption of an infant formula from these requirements.

In a notice of proposed rulemaking published in the Federal Register of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.
FDA requests approval for the information collections requirements contained in the following citations:

Section 412(d) of the Federal Food, Drug, and Cosmetic Act - Reporting

Requires submission to the agency of information specified in section 412(d) of the act. This includes, under section 412(d)(1) a quantitative formulation of the infant formula, a description of any reformulation or change in processing, assurances that the formula will not be marketed until it meets the requirements of subsection (b)(1) and (I) as demonstrated by testing required under subsection (b)(3), and assurances that the processing complies with subsection (b)(2). In

addition, under section 412(d)(2), after the first production of an infant formula, a written verification is required which demonstrates that the formula complies with requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(I), (b)(2)(B)(iii), (b)(3)(A), (b)(3)(C), and (I). Furthermore, under section 412(d)(3), if the manufacturer of an infant formula determines that a change in formulation or processing of the formula may affect whether the formula is adulterated under subsection (a), the manufacturer shall, before the first processing of the infant formula, make the submission to the Secretary required by section 412(d)(1).

21 CFR 106.100 - Record keeping

Requires maintenance and retention of records associated with microbiological/nutrient testing, quality control procedures, audits and investigation of consumer complaints.

21 CFR 106.120(b) - Reporting
Requires notification to the Agency when there is an infant formula that is adulterated or misbranded that may pose a risk to human health.

21 CFR 107.10(a) - Disclosure - Labeling

Requirement for specific nutrient information to be displayed on infant formula labeling.

21 CFR 107.20 - Disclosure - Labeling

Requirement for specific directions for use to be displayed on infant formula labeling.

21 CFR 107.50(e)(2) - Reporting

Requires notification to the Agency when there is an exempt infant formula that is adulterated or misbranded that may present risk to human health.

21 CFR 107.50(b)(3) - Reporting

Requirement for labeling to maintain exempt status of infant formula.

21 CFR 107.50(b)(4) - Reporting

Requirement for reformulation information when there is a change in ingredients or processes in order to maintain exempt status of infant formula.

21 CFR 107.50(c)(3) - Record keeping

Requirement for manufacturer to maintain records of its quality control procedures. (Regulatory language; burden in 21 CFR 106.100).

2. Information Users

This information is used by consumers when purchasing, storing and preparing infant formulas. The information is also used by firms and FDA to confirm that the nutrient requirements of the IFA have been met.

3. Improved Information Technology

Through the use of improved information technology the agency is always seeking ways to reduce the burden of maintaining quality control procedures and labeling requirements for infant formulas. Manufacturers of infant formula may submit infant formula notifications in electronic format.

4. Duplication of Similar Information

There is no duplicative information collection as a result of the infant formula regulations. The data recorded are specific to the individual processing facilities. No other regulation or information collection duplicates this effort. There are no similar data that can be used or modified for use.

5. Small Businesses

None of the manufacturers of infant formula fit the definition of small business. The regulations provide flexibility to manufacturers to verify nutrient levels by either testing during production or after processing. This provides the necessary flexibility to accommodate the various manufacturing methods and capabilities of both large and small manufacturers. FDA aids small businesses in dealing with the requirements through the Division of Education and Communication in the Center for Food Safety and Applied Nutrition (CFSAN) and through the scientific and administrative staffs of the agency.

6. Less Frequent Collection

The need for confirming nutrient levels of each batch of infant formula has been demonstrated each time a nutrient deficiency or overage has occurred since the passage of the IFA. These deficiencies or overages could have resulted in infant illnesses if the problem had gone undetected. However, due to the required testing by the manufacturers, discrepancies in nutrient levels have been found quickly and no illnesses have been reported to FDA resulting from inappropriate nutrient levels found in infant formulas since passage of the IFA.

7. Special Circumstances

Submissions are not made on a quarterly or regularly scheduled basis. Respondents submit information to the Agency as often as is required by the act, i.e., whenever they expect to market a new infant formula or when a major or minor change is made in the formulation or processing of an infant formula.

8. *Federal Register* Notice/Outside Consultation

This data collection is consistent with 5 CFR 1320.8. FDA personnel are regularly in contact with the International Formula Council and individual manufacturers. Discussions with manufacturers did not indicate problems with availability of required data or clarity of the regulation. Since the regulation has been in effect, each manufacturer of infant formula has been inspected annually. The inspection provides an opportunity for manufacturers to inform the Agency of any problems complying with these requirements. Manufacturers have not brought any significant problems to our attention.

In accordance with 5 CFR 1320.8(d), in the Federal Register of January 12, 2007 (72 FR 1539), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received no comments.

9. Payment/Gift to Respondent

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

10. Confidentiality

Information submitted to FDA under the infant formula regulations may contain trade secret and commercial confidential information. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by Section 301(j) of the act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Sensitive Questions

There are no questions of a sensitive nature in the data requirements for the infant formula regulations.

12. Burden Estimate (Total Hours and Wages)

The total estimated annual burden for this collection of information is 30,202 hours. FDA estimates the burden of this collection of information as follows:

a.) Reporting:

Table 1. – Estimated Annual Reporting Burden[1]

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses[2]	Hours per Response	Total Hours
Section 412(d)	5	13	65	10	650

of the act					
106.120(b)	1	1	1	4	4
107.10(a) and 107.20	5	13	65	8	520
107.50(b)(3) and (b)(4)	3	2	6	4	24
107.50(e)(2)	1	1	1	4	4
Total					1,202

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

[2] Manufacturers may submit infant formula notifications in electronic format.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

FDA estimates that it will receive 13 reports from 5 manufacturers annually under § 412(d) of the act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total for a total of 650 hours. For exempt infant formula, FDA estimates that it will receive 2 reports from 3 manufacturers annually, for a total annual response of 6 reports. Each report is estimated to take 4 hours per response for a total of 24 hours (see Table 1).

FDA estimates that compliance with the labeling requirements of §§ 107.10(a) and 107.20 will require 520 hours annually by 5 manufacturers. FDA also estimates that it will receive one notification under § 106.120(b) and one notification under § 107.50(e)(2). Each notification is expected to take four hours, for a total of eight hours.

b.) Record Keeping

Table 2. – Estimated Annual Recordkeeping Burden[1]					
21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeep-ing	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	400	20,000
107.50 (c)(3)	3	10	30	300	9,000
Total					29,000

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

FDA estimates that 5 firms will expend approximately 20,000 hours per year to fully satisfy the record keeping requirements in 21 CFR 106.100. It is estimated that 3 firms will expend approximately 9,000 hours per year to fully satisfy the record keeping requirements in 21 CFR 107.50(c)(3).

Costs to Respondents. There are 5 firms marketing infant formula and exempt infant formula in the United States. It has been estimated that the average hourly wage is $25 per hour. Doubling this wage to account for overhead costs, FDA estimates the hourly cost to respondents to be $50. The overall estimated cost incurred by the respondents is $1,510,100 (30,202 burden hours X $50/hr = $1,510,100).

13. Capital Costs (Maintenance of Capital Costs)

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

14. Cost to the Federal Government

FDA consumer safety officers review submitted notifications with input from technical reviewers. These costs are estimated at 3.3 person years (PY) or an approximate total of $257,766 ($78,111 X 3.3 PY = $257,766) The dollar estimate for FDA consumer safety officer wages corresponds roughly to GS level 13, step 6, which is $78,111 annually per the 2007 GS Salary Table.

FDA investigators currently inspect each manufacturing site annually and collect product labels for review. It is estimated that the agency expends approximately 1.3 PY on each firm for a total of 5.2 PY (1.3 PY X 4 = 5.2 PY) on enforcement activities associated with violations of these regulations. The costs are estimated at a total of $315,406 ($60,055 X 5.2 PY = $315,406). The dollar estimate for FDA investigator wages corresponds roughly to GS level 12, step 3, which is $60,055 annually per the 2007 GS Salary Table.

15. Program or Burden Changes

The total annual burden has increased from 25,968 hours to 30,202 hours. This increase is due to an increase in the estimated number of recordkeepers.

16. Publication and Tabulation Dates

The agency has no plans for publication of information 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"

N/A