

**INFANT FORMULA REQUIREMENTS**  
**Supporting Statement**  
OMB No.: 0910-0256

**A. Justification**

**1. Circumstances that Make Collection of Information Necessary**

In mid-1979, hypochloremic alkalosis, a syndrome associated with chloride deficiency, was diagnosed in a substantial number of infants. Most of the cases were traceable to the prolonged and exclusive use of a one of two soy formulas. The manufacturer of the soy formulas had reformulated these soy products by discontinuing the addition of salt (sodium chloride). In August 1979, the two infant formulas were recalled following the reports of serious injuries among infants.

Congress determined that greater regulatory control over the formulation and production of infant formula was necessary to protect infants using infant formula. It was clear that a total quality control program for the manufacture of infant formula was necessary to assure that each batch of the formula is uniform in composition and conformed to known nutrient requirements and that the reformulation of infant formulas should be reviewed to assure that this type of situation would not occur.

Consequently, Congress passed, and the President signed, the Infant Formula Act (IFA) of 1980 (section 412 of the Federal Food, Drug, and Cosmetic Act (the Act)). This Act provided clear authority for the Secretary to promulgate quality control regulations and regulations requiring a declaration of the nutrient levels on the label of infant formulas. Congress further strengthened the Act by passing the 1986 amendments to include exempt infant formula (section 412(h)(1)). (Attachment A).

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 IFA authorizes the Secretary to establish terms and conditions for the exemption of an infant formula from these requirements.

FDA requests approval for the information collections requirements contained in the following citations (Attachment B):

**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. How, by Whom, and for What Purpose the Information is Used**

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. Use of 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. Identification of Duplication and Similar Information Already Available**

A report by FDA to Congress identified all Federal programs involving infant formulas. No duplication of effort by Federal agencies was identified in the report. There are no similar data that can be used or modified for use.

**5. Small Business**

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 provided the necessary flexibility, based on the comments received, to accommodate the various manufacturing methods and capabilities of both large and small manufacturers. However, FDA does assist small business through the Office of Small Manufacturers Assistance.

**6. Consequences if Data were Collected Less Frequently**

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, ie. 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. Consultation Outside the Agency**

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), on Friday, October 17, 2003 (68 FR 59793), FDA published a 60-day notice for public comment (Attachment C) in the Federal Register. No comments were received from the public.

**9. Payment or Gifts**

No payment or gifts are offered to respondents for fulfilling their obligation to provide information.

**10. Confidentiality**

No assurance of confidentiality has been provided other than all information obtained by the agency will be reviewed within the guidelines given by 21 CFR 20.16 to determine confidentiality.

**11. Sensitive Questions**

The information required, does not involve any question of a sensitive nature.

**12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates**

The total estimated annual burden for this collection of information is 25,968 hours.

a.) Reporting:

The burden estimates are based on the number of submissions to FDA in the last 3 years. For nonexempt infant formula, the Center for Food Safety and Applied Nutrition (CFSAN) receives approximately 52 reports per year from 4 manufacturers for an average of 13 reports per respondent per year. Each report is estimated to take 10 hours per response for a total of 130 hours per respondent for a total of 520 hours. For exempt infant formula, CFSAN receives

approximately 6 reports per year from 3 manufacturers for an average of 2 reports per respondent. Each report is estimated to take 4 hours per response for a total of 8 hours per respondent (see table below).

TABLE 1--ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Food, Drug, and Cosmetic Act or 21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Section 412(d) (Food, Drug, and Cosmetic Act)	4	13	52	10	520
106.120(b)	4	0.25	1	4	4
107.10(a) 107.20	4	13	52	8	416
107.50(b)(3) and (4)	3	2	6	4	24
107.50(e)(2)	3	0.33	1	4	4
Total					968

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

b.) Record Keeping

It is estimated that 4 firms will expend approximately 16,000 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).

TABLE 2--ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping		Hours per record	Total Hours
106.100	4	10	40	4,000	16,000
107.50(c)(3)	3	10	30	3,000	9,000

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

**Costs to Respondents.** There are 4 firms marketing infant formula and exempt infant formula in the United States. It has been estimated that the average hourly wage is \$45 per hour<sup>1</sup>. The overall estimated cost incurred by the respondents is \$1,168,560 (25,968 burden hours X \$45/hr = \$1,168,560).

### **13. Cost to Respondents**

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

### **14. Cost to the Federal Government**

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<sup>1</sup>This estimate is derived from the Bureau of Labor Statistics National Compensation Survey March 2003 *Employer Costs for Employee Compensation* tables. The wages and salaries per hour worked were \$31.24 for “Executive, administrative, and managerial” employees and \$13.45 for “Administrative support, including clerical” employees. Doubling each of these wage estimates to include overhead costs and splitting the wage estimate equally between management and clerical workers, the average hourly wage is \$44.69.

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 \$235,950 ( $\$71,500 \times 3.3 \text{ PY} = \$235,950$ )<sup>2</sup>.

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 ( $1.3 \text{ PY} \times 4 = 5.2 \text{ PY}$ ) on enforcement activities associated with violations of these regulations. The costs are estimated at a total of \$286,000 ( $\$55,000 \times 5.2 \text{ PY} = 286,000$ )<sup>3</sup>.

**15. Change in Burden**

The total annual burden has increased from 25,560 hours to 25,968 hours. This increase is due to an increase in Total Annual Responses for non-exempt infant formulas.

**16. Publication of Collected Information**

There are no plans for publishing this information.

**17. Approval for NOT Displaying Expiration Date**

We are not seeking approval for NOT displaying the expiration date.

**18. Exception to the Certification Statement; Item 19, OMB Form 83-I.**

There are no exceptions to the certification statement.

**B. Collections of Information Employing Statistical Methods**

The collection of information required under the provisions of this regulation does not employ statistical methods.

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<sup>2</sup> The dollar estimate for FDA consumer safety officer wages corresponds roughly to GS level 13, step 6.

<sup>3</sup> The dollar estimate for FDA investigator wages corresponds roughly to GS level 12, step 3.