U.S. Food and Drug Administration

Infant Formula Requirements Under the Federal Food,
Drug, and Cosmetic Act; and 21 CFR Parts 106 and 107

OMB Control No. 0910-0256

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: In its last approval under the information collection OMB instructed FDA to report findings regarding the deployment of the collection instrument "electronic Form FDA 3978." We have discussed this under *Question 8*, below.

1. Circumstances Making the Collection of Information Necessary

This information collection was established to support Food and Drug Administration (FDA, us or we) regulations. Statutory provisions for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C Act, the act) were enacted to protect the health of infants and include specific current good manufacturing practice (CGMP) and labeling requirements. Section 412 of the FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify FDA when a batch of infant formula that has left its control may be adulterated or misbranded, and keep distribution records. Notification requirements are also included in the regulations regarding the quantitative formulation of the infant formula; a description of any reformulation or change in processing; assurances that the formula will not be marketed until regulatory requirements are met as demonstrated by specific testing; and assurances that manufacturing processes comply with the regulations. The regulations are codified at 21 CFR Part 106: *Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications*; and 21 CFR Part 107: *Infant Formula*.

To assist respondents with the requisite reporting and notification requirements we developed electronic Form FDA 3978, which serves as a reporting portal or Infant Formula Tracking System (IFTrack). Manufacturers of infant formula use the collection instrument to submit reports and notifications in a standardized format to FDA. Manufacturers that prefer to submit paper submissions in a format of their own choosing still have the option to do so. By using Form FDA 3978 however, respondents are prompted to organize submissions in a standardized format that ensures the collection of only that information needed for review. Screenshots of draft Form FDA 3978 and instructions remain available for comment at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.

We therefore request extension of OMB approval for the information collection provisions under 21 CFR Parts 106 and 107, and associated Form FDA 3978.

2. Purpose and Use of the Information Collection

We use the information collection to determine industry compliance with agency regulations. The requirements implement public health protection provisions of the act applicable to infants and all infant formula. Disclosures included in the information collection are used by consumers when purchasing, storing, and preparing infant formula to help ensure its safe use.

Description of Respondents: Respondents to the information collection are manufacturers of infant formula. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

There are few respondents to the information collection and we believe most all will use electronic means to fulfill the reporting requirements. Paper-based submissions are still accepted, however we think using Form FDA 3978 to satisfy the requirements will facilitate both respondents' submissions and our review. In addition to Form FDA 3978, we maintain links on the internet that provide infant formula guidance documents and regulatory information. The website is available at: https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/infantformula/default.htm

4. Efforts to Identify Duplication and Use of Similar Information

We have reviewed our active inventory and are unaware of duplicative information collection. Information collection provisions associated with infant formula recall regulations under 21 CFR Part 107; Subpart E are approved under OMB Control No. 0910-0188.

5. Impact on Small Businesses or Other Small Entities

We believe no undue burden is imposed on small entities. In addition to the resources referenced at Question 3, we assist small businesses in complying with our regulations through small business representatives, and scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/oc/industry/.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements and occurs on an occasional basis.

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

   There are no special circumstances for this collection of information.

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

   In accordance with 5 CFR 1320.8(d), we published a notice in the Federal Register of November 15, 2017 (82 FR 52927), requesting public comment for the information collection. No comments were received. In addition and as noted previously, there are few respondents to the information collection with whom we regularly engage. Since implementing the use of Form FDA 3978 we have received positive feedback from respondents through informal communications. Previously, respondents to the collection complied with the regulations by submitting individualized reports either electronically or using traditional mail, and used freestyle formatting with regard to the information. Currently, while most respondents utilize electronic Form FDA 3978 to report information to FDA, those respondents who export infant formula still utilize paper submissions such as registration information. Because the regulations do not currently mandate electronic reporting, we will continue to accept these paper-based submissions. Also, we continue to invite comment on suggested ways the collection instrument might be improved.

9. Explanation of Any Payment or Gift to Respondents

   No payments or gifts are associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

    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 FD&C 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. Justification for Sensitive Questions

    This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

    These estimates are based on recent analyses in support of rulemaking to establish GMP requirements and the addition of selenium to the list of required nutrients and establish minimum and maximum levels in infant formula. They are also based on our experience

with the information collection to which there are few respondents. We estimate the burden as follows:

12 a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Reporting Burden[1]

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

FD&C Act or 21 CFR Parts 106 and 107	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Reports; Section 412(d) of the FD&C Act	5	13	65	10	650
Notifications; § 106.120(b)	1	1	1	4	4
Reports for exempt infant formula; § 107.50(b)(3) and (4)	3	2	6	4	24
Notifications for exempt infant formula;§ 107.50(e)(2)	1	1	1	4	4
Requirements for quality factors growth monitoring study exemption; § 106.96(c)	4	9	36	20	720
Requirements for quality factors--PER exemption; § 106.96(g)	1	34	34	12	408
New infant formula registration; § 106.110	4	9	36	0.50 (30 mins.)	18
New infant formula submission; § 106.120	4	9	36	10	360
Total					2,188

We estimate we will receive 13 reports from 5 manufacturers annually under section 412(d) of the FD&C Act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours (row 1 of Table 1). We also estimate that we receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours (row 2 of Table 1).

For exempt infant formula, we estimate that we receive two reports from three manufacturers annually under § 107.50(b)(3) and (4), for a total annual response of six reports. Each report is estimated to take 4 hours per response for a total of 24 hours (row 3 of Table 1). We also estimate that we receive one notification annually under § 107.50(e)(2) and that the notification takes 4 hours to prepare, for an estimated burden of 4 hours (row 4 of Table 1).

We estimate that 4 firms submit 36 exemptions annually and that each exemption will take 20 hours to assemble. Therefore, we calculate 36 exemptions x 20 hours = 720 hours as the estimated burden for § 106.96(c) (row 5 of Table 1).

We estimate that the infant formula industry annually submits 35 Protein Efficiency Ratio (PER) submissions. For the submission of the PER exemption, we estimate that the infant formula industry submits 34 exemptions per year and that each exemption takes supporting staff 12 hours to prepare. Therefore, we calculate 34 exemptions x 12 hours per exemption = 408 hours to fulfill the requirements of § 106.96(g) (row 6 of Table 1).

We estimate that four firms each use one senior scientist or regulatory affairs professional who needs 30 minutes to gather and record the required information for an infant formula registration pursuant to § 106.110. We estimate that the industry annually registers 35 new infant formulas, or an average of 9 registrations per firm. Therefore, we calculate the annual burden as 36 registrations x 0.5 hour per registration = 17.5 (rounded to 18) hours (row 7 of Table 1).

We estimate that four firms each use one senior scientist or regulatory affairs professional who needs 10 hours to gather and record information needed for infant formula submissions pursuant to § 106.120. This estimate includes the time needed to gather and record the information the manufacturer uses to request an exemption under § 106.91(b)(1)(ii), which provides that the manufacturer includes the scientific evidence that the manufacturer is relying on to demonstrate that the stability of the new infant formula will likely not differ from the stability of formula with similar composition, processing, and packaging for which there are extensive stability data. We estimate that 4 firms make submissions for 36 new infant formulas, or an average of 9 submissions per firm. Therefore, to comply with § 106.120, we calculate the annual burden as 36 submissions x 10 hours per submission = 360 hours (row 8 of Table 1). Thus, we estimate the total annual reporting burden is 2,188 hours.

Table 2 -- Estimated Annual Recordkeeping Burden[1, 2]

FD&C Act or 21 CFR Parts 106 and 107	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Burden Per Record	Total Hours
Part 106 – SUBPART B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106 – SUBPARTS C-G: Quality control; audits; quality factors; records and reports	5	726.8	3,634	6	21,818
Part 107 – SUBPART C; Exempt infant formulas	3	10	30	300	9,000
Total			0		0

[1] There are no capital costs or operating and maintenance costs associated with the information.
[2] Numbers have been rounded.

To estimate recordkeeping burden we considered the number of manufacturing facilities and the number of applicable tests for which recordkeeping requirements apply. Using these figures we applied an average burden distributed among respondents to the collection. Cumulatively we estimate the recordkeeping requirements total 40,232 hours.

Table 3 – Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Nutrient labeling; 21 CFR 107.10(a) and 107.20	5	13	65	8	520

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

We estimate compliance with labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by the five respondents.

12b. Annualized Cost Burden Estimate

We measure costs based on the best available information from government, industry, and academic sources. We list some common conventions used throughout the cost analysis here. All wage rates used come from the Bureau of Labor Statistics (BLS), Occupational Employment Statistics, May 2016, National Industry-Specific Occupational Employment and Wage Estimates (available at: http://www.bls.gov/oes/current/oes191012.htm).

The BLS estimate of a mean hourly wage rate for a Food Scientist and Technologist is $41.75. Wages are increased by 100 percent to account for overhead. Therefore, our estimate for the mean hourly wage rate for a food scientist and technologist is $83.50, which includes fringe benefits and other overhead. Our total estimate of the cost is $3,542,590, as noted in Table 4.

Table 4. --Estimated Cost			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Food Scientist and Technologist (Reporting)	2,188	$83.50	$182,698
Food Scientist and Technologist (Recordkeeping)	40,232	$83.50	$3,359,372
Food Scientist and Technologist (Third-party disclosure)	520	$83.50	$43,420
Total			$3,585,490

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total cost to the Federal government is estimated to be $981,052.40. FDA investigators must inspect each manufacturing site annually and collect product labels for review. We currently allocate resources consistent with the last approval period and therefore retain the current estimate. This figure assumes a wage rate for an FDA investigator corresponding to 2018 OPM wage data for employees in the Washington-Metropolitan Area ($86,984) and is multiplied by an estimated number of hours FDA expends in compliance activities to ensure safe infant formula.

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments. We believe burden associated with rulemaking (RIN 0910-AF27) establishing GMP requirements and labeling requirements to include selenium among the list of required nutrients and establish minimum and maximum levels in infant formula that became effective since last extension have now been realized. Accordingly, we removed ICs previously included as one-time burden. We also assume the realization of capital costs previously attributed to compliance with the new labeling requirements. Finally, we have consolidated recordkeeping provisions established by the rulemakings that had previously been itemized to reflect the impact of the regulatory changes. Cumulatively these adjustments reflect 10,809 fewer annual responses and 35,596 fewer burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

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

Display of the OMB Expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.