UNITED STATES FOOD & 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

Terms of Clearance: Approved with the understanding that existing collection 0910-0811 will be discontinued. OMB control number 0910-0811 was discontinued on March 19, 2019.

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations, and associated agency forms and guidance, pertaining to infant formula requirements. Statutory provisions for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) were enacted to protect the health of infants and include specific current good manufacturing practice (CGMP), labeling requirements and a number of reporting and recordkeeping 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 the manufactures' control may be adulterated or misbranded, and keep records of infant formula distribution. 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*.

We have issued regulations to implement the FD&C Act's requirements for infant formula in parts 106 and 107 (21 CFR parts 106 and 107). We also regulate the labeling of infant formula under the authority of section 403 of the FD&C Act (21 U.S.C. 343). Under our labeling regulations for infant formula in part 107, the label of an infant formula must include nutrient information and directions for use, and it sets forth the labeling requirements applicable to infant formula under section 403 of the FD&C Act. Failure to comply with any of the applicable regulations will render an infant formula misbranded under section 403 of the FD&C Act. The purpose of these labeling requirements is to ensure that consumers have the information needed to prepare and use infant formula appropriately.

While the infant formula regulations help ensure the consistent production of safe and nutritionally adequate infant formulas for healthy term infants, they apply with one narrow exception. Section 412(h)(1) of the FD&C Act exempts an infant formula represented and

labeled for use by an infant with an inborn error of metabolism, low birth weight, or who otherwise has an unusual medical or dietary problem from the requirements of sections 412(a), (b), and (c) of the FD&C Act. These formulas are customarily referred to as "*exempt infant formulas*." Section 412(h)(2) of the FD&C Act authorizes us to establish terms and conditions for the exemption of an infant formula from the requirements of sections 412(a), (b), and (c) of the FD&C Act. The terms and conditions for exempt infant formulas are in 21 CFR part 107 subpart C.

In support of exempt infant formulas, we have issued the agency guidance document entitled, "*Exempt Infant Formula Production: Current Good Manufacturing Practices (CGMPs), Quality Control Procedures, Conduct of Audits, and Records and Reports*." The guidance document includes our recommendation that manufacturers of exempt infant formulas follow, to the extent practicable, subparts A, B, C, D, and F of 21 CFR part 106 and is located at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-exempt-infant-formula-production.

To assist respondents with the requisite reporting and notification requirements, we have also developed electronic Form FDA 3978, which serves as a reporting portal or Infant Formula Tracking System (IFTRACK). Manufacturers of infant formula may use this 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. Form FDA 3978 prompts a respondent to organize their submissions in a standardized format for only that information needed for review. Screenshots of draft Form FDA 3978 and instructions are available at http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/InfantFormula/default.htm.

We therefore request extension of OMB approval for the information collection provisions set forth in 21 CFR parts 106 and 107, and the associated guidance and Form FDA 3978, as discussed in this supporting statement.

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 FD&C 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 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. Other 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 Item 3 (above), we assist small businesses in complying with our regulations through small business representatives, and scientific and administrative staffs within the agency. Additional assistance is available for small businesses via the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory 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 December 2, 2020 (85 FR 77469), requesting public comment for the information collection. Two comments were received providing general support for infant formula labeling; however, neither comment requested revision to the burden estimates

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)).

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII is submitted via Form 3978, "*The New Infant Registration and Submission*" is name, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. The form also allows submission of potentially identifying work information including job title and credentials.

11. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Activity; 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

Table 1.--Estimated Annual Reporting Burden[1]

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

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

FD&C Act or 21 CFR Part	No. of Recordkeepers	No. of Records Per Recordkeeper	Total Annual Records	Average Burden Per Recordkeeping	Total Hours
Part 106--subpart B: CGMP Requirements	5	429.8	2,149	4.4	9,414
Part 106--subparts C through 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
Exempt infant formula production; GMP; audits, recordkeeping, and reports	3	634	1,902	45	85,590
Total					125,822

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

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

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Avg. Burden per Disclosure	Total Hours
Nutrient labeling; §§ 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.

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 2019, 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 $42.05. 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 $84.10, which includes fringe benefits and other overhead. Our total estimate of the cost is $10,809,373, as noted in Table 4.

Table 4.--Annual Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Food Scientist and Technologist (Reporting)	2,188	$84.10	$184,011
Food Scientist and Technologist (Recordkeeping)	125,822	$84.10	$10,581,630
Food Scientist and Technologist (Third-party disclosure)	520	$84.10	$43,732
Total			$10,809,373

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 $1,049,187. 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 adjusts only to account for change in wages. This figure assumes a wage rate for an FDA investigator corresponding to 2021 OPM wage data for employees in the Washington-Metropolitan Area at a GS-12/3 ($93,013) 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

Based on a review of this information collection since our last request for OMB approval, we have made no adjustments. However, we corrected a nominal calculation error which results in a decrease of 2 responses and 308 hours annually. The correction is found in the IC element corresponding to "*Exempt Infant Formula: Notification Requirements*."

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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.