Third-Party Disclosure Requirements for Selenium in Infant Formula
OMB Control No. 0910-0256

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Section 412(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350a(i)) establishes requirements for the nutrient content of infant formulas. Under section 412(i)(2) (21 U.S.C. 350a(i)(2)), the Secretary of Health and Human Services is authorized to revise the list of required nutrients and the required level for any required nutrient, which authority has been delegated to the Commissioner of Food and Drugs. The table in section 412(i) and FDA regulations, 21 CFR 107.100, specify that infant formulas must contain 29 nutrients; minimum levels for each nutrient and maximum levels for nine of the nutrients are also specified.

At the time FDA established nutrient specifications for infant formula; selenium was not recognized as an essential nutrient and was not one of the nutrients required by statute in infant formula. As explained in detail below, selenium has subsequently been recognized as an essential nutrient. Therefore, we are proposing to amend the nutrient specifications for infant formula in § 107.100 to include selenium as a required nutrient and to establish minimum and maximum values for selenium. The proposed rule, if finalized, would revise §107.10(a) to require that selenium be listed in the nutrient list on the label for all infant formulas. In particular, in the nutrient list, selenium would be required to be listed between iodine and sodium and the amount per 100 calories declared; and, because selenium would be a required ingredient in infant formula, selenium would also be required to be declared in the formula's ingredient statement by its common or usual name and positioned according to the descending order of its predominance in the formula, under § 101.4. The present version of § 107.10(a) is approved by OMB in accordance with the PRA and has been assigned OMB control number 0910-0256. This proposed rule, if finalized, would modify the information collection associated with the present version of § 107.10(a) by adding 23 hours to the burden associated with the collection.

FDA requests the revision of OMB approval of the information collection provisions in the following citation:

21 CFR 107.10(a) - Third Party Disclosure

Requires specific nutrient information be included in the labeling of infant formula.

2. Purpose and Use of the Information Collection

   The nutrient information disclosed by manufacturers on the infant formula label is necessary to inform purchasers of the value of the infant formula. 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 FD&C Act have been met.

   Description of Respondents: Respondents to this 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

   FDA estimates that 100% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

   This data collection does not duplicate any other information that is already available to FDA.

5. Impact on Small Businesses or Other Small Entities

   FDA finds that, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), this proposal, if finalized, will not have a significant impact on a substantial number of small entities, as only one firm is affected by this rule and it is considered large by Small Business Administration standards.

6. Consequences of Collecting the Information Less Frequently

   Respondents will respond on an occasional basis**,** as prescribed by the proposed rule.

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

   FDA published a proposed rule on April 16, 2013 (78 FR 22442) requesting public comment on the information collection. No comments were received regarding the information collection topics solicited.

9. Explanation of Any Payment or Gift to Respondents

   There are no payments or gifts to respondents associated with this collection of information.

10. Assurance of Confidentiality Provided to Respondents

There is no assurance of confidentiality associated with the proposed requirement that selenium be listed in the nutrient list on the label for all infant formulas. 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. Justification for Sensitive Questions

This collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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

Table 1.--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	Total Capital Cost
§107.10 Nutrient labeling for infant formula	1	46	46	0.5 (30 mins.)	23	$765,439

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

This proposed rule, if finalized, would modify the information collection associated with the present version of § 107.10(a) by adding 23 hours to the burden associated with the collection. A manufacturer not in compliance with the new minimum and maximum levels for selenium in infant formula would be required to make a one-time change to the nutrient list information disclosed to consumers on the label of its infant formula, to account for the required change in the amount of selenium in its products.

FDA tentatively concludes that the additional burden to disclose selenium in the ingredient statement resulting from the proposed amendment of §107.10 would be negligible because all U.S. infant formula manufacturers currently add selenium as an ingredient to their infant formula products, and all manufacturers currently disclose the selenium in the ingredient statement, as specified by §101.4. Additionally, all manufacturers currently disclose selenium in the nutrient list, as required by §107.10(b)(5). Only one manufacturer produces infant formula that would not meet the requirements of this rule, if finalized, and would thus need to be reformulated. Under proposed §107.10(a)(2), this one manufacturer would need to make a one-time labeling

change to modify its nutrient list to account for the addition of more selenium to its infant formula.

The third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. Based upon its knowledge of food and dietary supplement labeling, FDA estimates that the affected manufacturer would require less than 0.5 hour per product to modify the label's nutrient list to reflect the addition of more selenium to the product. The Regulatory Impact Analysis estimates that this manufacturer produces 46 separate infant formulas that would need to be reformulated, and thus require relabeling. The one-time third-party disclosure burden for the proposed rule is estimated in table 1 of this document.

Additionally, because of the change in formulation of its products that would be required if the rule is finalized as proposed, a manufacturer would need to determine whether they are required to make a one-time submission to FDA before the first processing of its formulas, as required by section 412(d)(3) of the FD&C Act. This reporting requirement is approved by OMB under OMB control number 0910-0256. The current hour burden approved by OMB for section 412(d) of the FD&C Act is 10 hours per report. Based on the agency's experience with infant formula submissions, FDA estimates that the affected manufacturer will submit one report that will cover all 46 reformulated infant formulas. In a future request for extension of the 0910-0256 information collection, FDA will include the additional report in its estimates.

b. 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, Occupational Employment Statistics, May 2012, National Industry-Specific Occupational Employment and Wage Estimates (available at: http://www.bls.gov/oes/current/oes191012.htm).

Wages are increased by 50 percent to account for overhead. Food Scientist and Technologist: Our estimate for the mean hourly wage rate for a farm operator or manager is $46.26 including fringe benefits and other overhead.

First Year Cost			
Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Line Worker—Food Scientist	23	$46.26	$1,064

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

As estimated in the RIA for this proposed rule, the estimated capital cost related to this information burden is the cost of designing a revised label and incorporating it into the manufacturing process.

The final column of table 1 gives the estimated capital cost associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. The cost stated in table 1, $765,439, is based on the estimate in the Regulatory Impact Analysis under Option 3, which assumes that the proposed rule is finalized with an effective date of 1 year after publication. These costs are based on the estimation of the cost model that, over a longer period of time, any labeling change is more likely to be able to be coordinated with a change in a label that may already be scheduled, and will diminish the need to, for example, purchase and apply stickers to packages affected by the change.

14. Annualized Cost to the Federal Government

These activities will be covered by existing resource allocations. In the 2010 supporting statement, FDA estimated the annualized cost to the Federal government associated with the entire 0910-0256 information collection to be as follows. FDA consumer safety officers review submitted notifications with input from technical reviewers. The dollar estimate for FDA consumer safety officer wages corresponds roughly to GS level 13, step 6, which is $95,459 annually per the 2010 GS Salary Table. These costs are estimated at 3.3 person years (PY) or an approximate total of $315,014.70 ($95,459 X 3.3 PY = $315,014.70).

FDA investigators currently inspect each manufacturing site annually and collect product labels for review. The dollar estimate for FDA investigator wages corresponds roughly to GS level 12, step 3, which is $73,396 annually per the 2010 GS Salary Table. 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 $381,592 ($73,396 X 5.2 PY = $381,592). Thus, the total cost to the Federal government is $696,673.90.

15. Explanation for Program Changes or Adjustments

This proposed rule, if finalized, would modify the information collection 0910-0256 associated with the present version of § 107.10(a) by adding 23 hours to the burden associated with the collection.

16. Plans for Tabulation and Publication and Project Time Schedule

These information collection requirements will not be published, tabulated or manipulated.

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

Approval to not display the expiration date of OMB approval is not being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.