4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0545]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the information collection provisions of our infant formula regulations, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400T, Rockville, MD 20850, domini.bean@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Infant Formula Requirements--21 CFR Parts 106 and 107 (OMB Control Number 0910-0256)--Extension

Statutory requirements for infant formula under the Federal Food, Drug, and Cosmetic Act (the FD&C 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 FD&C Act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere to quality control procedures, notify us when a batch of infant formula that has left the manufacturers' control may be adulterated or misbranded, and keep records of distribution. We have issued regulations to implement the FD&C Act's requirements for infant formula in 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. The purpose of these labeling requirements is to ensure that consumers have the information they need to prepare and use infant formula appropriately.

In a notice of proposed rulemaking published in the Federal Register of July 9, 1996 (61 FR 36154), we proposed changes in our infant formula regulations, including some of those listed in tables 1, 2, and 3 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the Federal Register of April 28, 2003 (68 FR 22341) (the 2003 reopening), FDA reopened the comment period for the proposed rule. Interested persons were originally given until June 27, 2003, to comment on these issues and the 1996 proposal. However, in response to a request, the comment period was extended to August 26, 2003 (68 FR 38247, June 27, 2003). FDA again reopened the comment period on August 1, 2006 (71 FR 43392) (the 2006 reopening) for 45 days to accept comment on a limited set of

issues. In a notice of proposed rulemaking published in the Federal Register of April 16, 2013 (78 FR 22442), we proposed to amend our regulations on nutrient specifications and labeling for infant formula to add the mineral selenium to the list of required nutrients and to establish minimum and maximum levels of selenium in infant formula. The document also included revised burden estimates for the proposed changes and solicited public comment. In the interim, FDA is seeking an extension of OMB approval for the current regulations so that we can continue to collect information while the proposals are pending.

We estimate the burden of this collection of information as follows:

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

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
Section 412(d) of the FD&C Act	5	13	65	10	650
§ 106.120(b)	1	1	1	4	4
§ 107.50(b)(3) and (b)(4)	3	2	6	4	24
§ 107.50(e)(2)	1	1	1	4	4
Total					682

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

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

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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.

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

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

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

In compiling these estimates, we consulted our records of the number of infant formula submissions received in the past. All infant formula submissions may be provided to us in

electronic format. The hours per response reporting estimates are based on our experience with similar programs and information received from industry.

We estimate that 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. We also estimate that we will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, we estimate that we will receive two reports from three manufacturers annually under §§ 107.50(b)(3) and (b)(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. We also estimate that we will receive one notification annually under § 107.50(e)(2) and that the notification will take 4 hours to prepare.

We estimate that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100 and that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

We estimate compliance with our labeling requirements in §§ 107.10(a) and 107.20 requires 520 hours annually by 5 manufacturers.

Dated: May 9, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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