4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0814]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0256. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

OMB Control Number 0910-0256--Revision

This information collection supports FDA 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 (FD&C Act) were enacted to protect the health of infants and include specific current good manufacturing practice (CGMP), labeling (disclosure), 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 document the adherence to quality control procedures, notify FDA when a batch of infant formula that has left the manufacturers' 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 found in 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 revised the information collection as part of the Federal Government's response to address ongoing disruptions in the infant formula supply. We communicated our initial efforts to address the infant formula shortage in the May 2022 guidance entitled "Infant Formula Enforcement Discretion Policy: Guidance for Industry" (May 2022 guidance; available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-enforcement-discretion-policy). To clarify whether products currently subject to enforcement discretion would be able to remain on the market, we issued the September 2022 guidance entitled "Infant Formula Transition Plan for Exercise of Enforcement Discretion:

Guidance for Industry" (September 2022 guidance; available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-infant-formula-transition-plan-exercise-enforcement-discretion). The September 2022 guidance sets out a pathway for manufacturers of infant formula that began marketing infant formula products in the United States after receiving a letter of enforcement discretion based on information provided in response to the May 2022 guidance to seek to continue marketing such products under enforcement discretion while they work to bring their infant formula products fully into compliance with applicable requirements.

In the *Federal Register* of October 6, 2022 (87 FR 60689), FDA announced that we had requested, and OMB had approved, emergency processing of the proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13) and invited public comment, instructing comments be submitted to OMB. No comments have been received. On our own initiative, however, we are also revising the collection to account for voluntary notifications pertaining to product samples found to be positive for *Cronobacter* spp. or *Salmonella*, even if the affected lot(s) have not been distributed. FDA has requested this information to help prevent future *Cronobacter* spp. illnesses associated with powdered infant formula. As part of a constituent update, available at https://www.fda.gov/food/cfsan-constituent-updates/fda-calls-enhanced-safety-measures-letter-powdered-infant-formula-industry, we issued a letter on March 8, 2023, to share current information to assist industry in improving the microbiological safety of powdered infant formula. As communicated in the letter, we shared the information with the expectation that infant formula manufacturers, packers, distributors, exporters, importers, and retailers will act to mitigate potential food safety risks in powdered infant formula in accordance with FDA regulations while further striving to improve operations, especially given the critical nature of these products.

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

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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Submit information in accordance with timing and content schedule discussed in guidance document for both exempt and non-exempt infant formulas	115	1	115	24	2,760
Letter of Intent	11	1	11	5	55
Plan to Meet Applicable Infant Formula Requirements	11	1	11	90	990
Voluntary Submission of sample results as described in constituent update of March 8, 2023	20	1	20	0.25 (15 minutes)	5
Total					3,810

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

Our estimate is based on submissions received in response to the May 2022 guidance, for which we account for 115 respondents, each of whom submitted 1 request. We assume it requires an average of 24 hours to prepare each submission, and therefore calculate a total of 2,760 burden hours (115 requests × 24 hours). Although originally we assumed 15 respondents would initiate requesting enforcement discretion, out of those 115 respondents, we have issued letters of enforcement discretion to 12 of them. We received letters from 11 of these respondents indicating their intent to bring their products fully into compliance with applicable regulatory requirements and requesting that we continue to exercise enforcement discretion in the interim, and have therefore adjusted the number of respondents associated with the corresponding activities accordingly. We assume each request requires an average of 5 hours to prepare, for a total of 55 burden hours (11 letters × 5 hours). We estimate these same respondents will then submit a compliance plan and assume each plan will require an average of 90 hours to prepare, for a total of 990 burden hours (11 plans × 90 hours).

We estimate the burden associated with the voluntary notification of positive sampling results as discussed in our March 8, 2023, letter to be 20 responses and 5 hours annually, assuming 15 minutes is necessary for the completion of this activity. We also assume respondents will utilize established notification methods found on our website or by contacting the FDA district office in which the positive sampling results have occurred.

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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