

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

[Docket No. 02N-0055]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Infant Formula Recall Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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.

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**Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, and 107.280  
(OMB Control Number 0910-0188)—Extension**

Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall, by regulation, prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA's infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with an FDA approved notice of recall. Section 107.240 requires the recalling firm to: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§ 107.250). Where the recall strategy or

implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§ 107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§ 107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA's ability to ensure that recalls are conducted properly would be greatly impaired.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	3	1	3	4,500	13,500
107.240	3	1	3	1,482	4,446
107.250	3	1	3	120	360
107.260	3	1	3	650	650
Total					18,956

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in § 107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a

matter of routine business practice. The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been three recalls in the last 3 years, or one recall annually.

Dated: 5-31-02

May 31, 2002.

Margaret M. Dotzel

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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