

Dated: April 26, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0029]

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

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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.

**DATES:** Fax written comments on the collection of information by June 2, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (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.

#### Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 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 (21 CFR part 107), subpart E) implement these statutory provisions.

Section 107.230 requires each recalling firm to conduct an infant formula recall with the following elements: (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 a copy of the notice. Section 107.240 requires the recalling firm to conduct an infant formula recall with the following elements: (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.

In the **Federal Register** of February 1, 2005 (70 FR 5188), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of the 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	2	1	2	4,500	9,000
107.240	2	1	2	1,482	2,964
107.250	2	1	2	120	240
107.260	1	1	1	650	650
Total					12,854

<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, on average, two infant formula recalls per year for the past 3 years.

Dated: April 26, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0031]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification for a New Dietary Ingredient**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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.

**DATES:** Fax written comments on the collection of information by June 2, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (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.

**Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910-0330)—Extension**

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides that a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to FDA (as delegate for the Secretary of Health and Human Services) upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be

expected to be safe at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. FDA's regulations at part 190, subpart B (21 CFR part 190, subpart B) implement these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutritional Products, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contains the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

In the **Federal Register** of February 7, 2005 (70 FR 6444), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
190.6	71	1	71	20	1,420

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

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program, because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the

act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours of work per submission.

During the past 3 fiscal years, from October 1, 2002, through September 30,

2004, FDA received an average of 47 notifications per year with an average of 1 notification per submitting manufacture or distributor. In comparison, during the previous 3 fiscal years, from October 1, 1999, through September 30, 2001, FDA received an average of 23 notifications per year with an average of 1 notification per submitter. The annual average number