

OMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Display Date 1-12-04
Publication Date 1-13-04
Certifier G. Penley

[Docket No. 2003N-0463]

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) 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 *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: The Office of Management and Budget (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.

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 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 act (21 U.S.C. 350a) requires manufacturers of infant formula to establish and adhere 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 distribution. FDA has issued regulations to implement the act's requirements for infant formula in 21 CFR part 106 and part 107 (21 CFR part 107). FDA also regulates the labeling of infant formula under the authority of section 403 of the act (21 U.S.C. 343). Under the 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 that published in the **Federal Register** of July 9, 1996 (61 FR 36154), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The document included revised burden estimates for the proposed changes and solicited public comment. In the interim, however, FDA is seeking an extension of OMB approval for the current regulations so that it can continue to collect information while the proposal is pending.

In the **Federal Register** of October 17, 2003 (68 FR 59793) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
Section 412(d) of the act	4	13	52	10	520
106.120(b)	4	0.25	1	4	4
107.10(a) and 107.20	4	13	52	8	416
107.50(b)(3) and (b)(4)	3	2	6	4	24
107.50(e)(2)	3	0.33	1	4	4
Total					968

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

² Manufacturers may submit infant formula notifications in electronic format.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
106.100	4	10	40	4,000	160,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					250,000

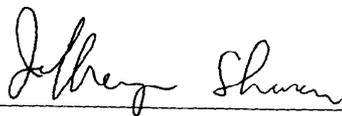
¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per

response are based on estimates from experienced persons in the agency and in industry.

Dated: JAN 6 2004

January 6, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

COPIES OF ORIGINAL

