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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00N-1441]

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

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. 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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection regarding the manufacturer of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

**DATES:** Submit written comments on the collection of information by *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (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:** Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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 a proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s 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 (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 manufacturer’s 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 parts 106 and 107 (21 CFR parts 106 and 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 document 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 information. 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.

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

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

Federal Food, Drug, and Cosmetic Act (the act) or 21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the act	4	7	28	10	280
106.120(b)	4	0.25	1	4	4
107.10(a) and 107.20	4	7	28	8	224
107.50(b)(3) and (b)(4)	3	4	12	4	48
107.50(e)(2)	3	0.33	1	4	4
Total					560

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	4	10	40	4,000	16,000
107.50(c)(3)	3	10	30	3,000	9,000
Total					25,000

<sup>1</sup> 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: August 11, 2000



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William K. Hubbard,  
Senior Associate Commissioner  
for Policy, Planning, and Legislation.

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