DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0528]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection regarding the manufacture of infant formula, including infant formula labeling, quality control procedures, notification requirements, and recordkeeping.

DATES: Submit written or electronic comments on the collection of information by March 13, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 an existing 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 these topics: (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—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 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 notice of proposed rulemaking published in the **Federal Register** of July 9, 1996 (61 FR 36154) (the 1996 proposed rule), FDA proposed changes in the infant formula regulations, including some of those listed in tables 1 and 2 of this document. The 1996 proposed rule 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[1]

Section of the 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	5	13	65	10	650
21 CFR 106.120(b)	5	0.25	1.25	4	5
21 CFR 107.10(a) and 107.20	5	13	65	8	520
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	3	0.33	1	4	4
Total					1,203

[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 BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	4,000	200,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					290,000

[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: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–331 Filed 1–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 340B of the Public Health Service Act implements a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. The purpose of this notice is to inform interested parties of proposed guidelines regarding contract pharmacy services that will allow covered entities to utilize contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program.

DATES: The public is invited to comment on the proposed guidelines by March 13, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

A. Background

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Previous guidelines pertaining to contract pharmacy services for the 340B drug pricing program (61 FR 43549, Aug. 23, 1996) stated that a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services.

In 2001, HRSA established Alternative Methods Demonstration Projects (AMDPs) which allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the following: (1) The use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities. The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients. From the time of the program's inception until the end of April 2006, a total of 18 AMDPs were approved. Of those, 11 utilize a multiple contract pharmacies model, four establish a network of 340B covered entities, one is a combination of the network model and the multiple contract pharmacies model, one utilizes a contract pharmacy to supplement an in-house pharmacy, and one utilizes multiple contract pharmacies to supplement an in-house pharmacy. All but one of the projects is currently ongoing. A condition of AMDP approval is the requirement that the approved demonstration project be audited annually by an independent, outside auditor for drug diversion and duplicative discounts under Medicaid. The results of the audits are required to be reported to the Office of Pharmacy Affairs (OPA). To date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program.

HRSA, acting through OPA, is proposing new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites and the utilization of a contract pharmacy to supplement in-house pharmacy services that were previously limited to approved AMDPs. This proposed change is due to the success of the AMDPs, and the urging of safety net providers who wish to utilize alternatives to the single entity site/single pharmacy location contractor model to provide broader access to 340B discounted drugs to eligible patient populations. Other than permitting these specified models, HRSA is not proposing other substantive changes to the contract pharmacy guidelines. The AMDP process will continue for those covered entities wishing to develop 340B networks of covered entities. OPA will continue to review the utilization of network demonstration projects and consider adapting the rules to include them in the future. Of particular importance is the continued requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute.

These proposed guidelines replace all sections of previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services,'' 61 FR