FORMAT

Order	Drug Facts	Minimal Column	Column Plus
Warning first			
Indication first			

The Order manipulation will vary the primacy of the boxed warning information versus the paragraph about the uses to the drug. In terms of Format, the Drug Facts format will follow the conventions of the existing OTC labeling. The Minimal Column condition will contain information in two columns with only basic information in the sections regarding information patients should tell their doctors. The Column Plus condition will also present information in two columns, but will include additional contextual information in the sections about what information patients should report to their doctors.

Participants with relevant medical conditions will be randomly assigned to one of the six experimental conditions and each participant will see only one version of the patient information. Participants will be prescreened to represent a range of health literacy levels, including a portion with low literacy. Thus, all participants in the study will have been diagnosed with rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis and at least 30 percent of the sample will fall in the lower range of literacy. Because the average reading level in the United States is estimated to be 8th grade[9] and it is recommended that consumer medication information be written at a 5th grade reading level,[10] the low literate cohort will consist of consumers who have 5th to 8th grade reading skills. Education level is not a reliable substitute for literacy testing. At screening, the participants will be assessed for literacy level using a validated instrument.

An additional small study will be conducted via the Internet to determine whether electronic prototype presentation alters the processing of the information in any way. Two-hundred individuals with the same characteristics of the original sample (e.g., medical condition and literacy levels) will be recruited over the Internet and will complete the same questionnaire as original participants.

FDA is undertaking this study because it does not yet have sufficient evidence-based research relating to patient needs, or whether those needs are being effectively met. Research related to the functionality and effectiveness of written patient information consistently identifies the importance of performance-based testing as well as content based testing, which enables the evaluation of materials in order to assure their utility and identify issues in content format, or design. Development of new prescription drug patient materials must be based on consumer testing that focuses on utility to the patient and comprehension of material in the broadest audience possible. FDA has developed three prototypes in order to user test prescription drug information with consumers in order to achieve this goal. For further information, contact Elizabeth Berbakos (see **FOR FURTHER INFORMATION CONTACT**).

The burden table reflects up to three pretests of 180 individuals each, 900 participants in the main study, and 200 participants in the followup study involving electronic administration.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
	540	1	540	20/60	178
	900	1	900	25/60	369
	200	1	200	25/60	82
Total					629

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

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10359 Filed 5–3–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

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

[9] Cotunga N., C.E. Vickery, K.M. Carpenter-Haefele, "Evaluation of Literacy Level of Patient Education Pages in Health-Related Journals," *Journal of Community Health*, 30(3), 213–219, 2005.

[10] Andrus, M.R., M.T. Roth, "Health Literacy: A Review," *Pharmacotherapy*, 22(3), 282–302, 2002.

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 July 6, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. 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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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 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 notice of proposed rulemaking 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, 2, and 3 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Federal Food, Drug, and Cosmetic Act or 21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 412(d) of the act	5	13	65	10	650
21 CFR 106.120(b)	1	1	1	4	4
21 CFR 107.50(b)(3) and (b)(4)	3	2	6	4	24
21 CFR 107.50(e)(2)	1	1	1	4	4
Total					682

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

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	400	20,000
107.50 (c)(3)	3	10	30	300	9,000

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Total					29,000

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

TABLE 3.—THIRD PARTY DISCLOSURE REQUIREMENTS[1]

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
21 CFR 107.10(a) and 107.20	5	13	65	8	520

[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. All infant formula submissions to FDA may be provided in electronic format. The hours per response reporting estimates are based on FDA's experience with similar programs and information received from industry.

FDA estimates that it will receive 13 reports from 5 manufacturers annually under section 412(d) of the act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. FDA also estimates that it will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, FDA estimates that it will receive two reports from three manufacturers annually under § 107.50(b)(3) and (b)(4), for a total annual response of six reports. Each report is estimated to take 4 hours per response for a total of 24 hours. FDA also estimates that it will receive one notification under § 107.50(e)(2). The notification is expected to take 4 hours per response, for a total of 4 hours.

FDA estimates that 5 firms will expend approximately 20,000 hours per year to fully satisfy the record keeping requirements in § 106.100. It is estimated that 3 firms will expend approximately 9,000 hours per year to fully satisfy the record keeping requirements in § 107.50(c)(3).

FDA estimates that compliance with the labeling requirements of §§ 107.10(a) and 107.20 will require 520 hours annually by 5 manufacturers.

Dated: April 28, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–10360 Filed 5–3–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0507]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

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 3, 2010.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0530. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *Elizabeth.Berbakos@fda.hhs.gov*, 301–796–3792.

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.

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format—OMB Control Number 0910–0530—Extension

FDA is requesting that OMB extend approval under the Paperwork Reduction Act (44 USC 3501–3520) for the information collection resulting from the requirement that the content of labeling for prescription drug products be submitted to FDA electronically in a form that FDA can process, review, and archive. This requirement was set forth in the final rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (December 11, 2003; 68 FR 69009), which amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs) (21 CFR 314.50(l)(1)(i)), including supplemental NDAs, abbreviated new drug applications (ANDAs) (21 CFR 314.94(d)(1)(ii)), including supplemental ANDAs, and annual reports (21 CFR 314.81(b)(2)(iii)(b)) (the final rule also applied to certain Biologics License Applications, but the information collection for these requirements is not part of this OMB approval request).

This OMB approval request is only for the burden associated with the electronic submission of the content of labeling. The burden for submitting labeling as part of NDAs, ANDAs, supplemental NDAs and ANDAs, and annual reports, has been approved by OMB under Control Number 0910–0001.

When we last requested that OMB extend approval for this information collection (see the **Federal Register** of March 29, 2006 (71 FR 15752)), we received several comments. Generally,