

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0398]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

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.

Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling (OMB Control No. 0910–0340)

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products. The rule requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by OMB because they are “originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and therefore do not constitute a “collection of information” under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 (21 CFR 201.66) of the labeling requirements requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d) of that section. FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the labeling requirements. Therefore, the majority of respondents will be able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), the agency stated that of the 39,310 stockkeeping units (SKUs) (individual products, packages, and sizes) currently marketed under a final monograph, approximately 32 percent, or 12,573 products, may necessitate labeling changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required

to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average of, 4 hours, for a total of 50,292 hours per year. The burden was expected to be a one-time burden.

The agency stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs currently marketed, or 26,737 products, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents, who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with this rule. FDA estimated that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. The burden was expected to be a one-time burden.

Finally, the agency estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments will be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) will be required for labeling changes under 21 CFR 201.66(c) and (d), which averages to 8.5 submissions per respondent. The agency estimated that each submission will take an average of 2 hours to prepare for a total of 1,040 hours annually. The burden was also expected to be a one-time burden.

Since the final rule was issued on March 17, 1999, the agency has extended the April 16, 2001, compliance date by 1 year to April 16, 2002 (with a corresponding extension of the April 16, 2002, compliance date for products with annual sales of less than \$25,000 to April 16, 2003) (65 FR 38191, June 20, 2000). During this time, the agency has published only one major final rule (which has had its effective date extended from May 21, 2001, to December 31, 2002) (65 FR 36319, June 8, 2000) and several minor amendments to existing final rules. These monograph amendments have an effective date of May 16, 2002, so that the relabeling required by the amendments may be coordinated with the relabeling required by the OTC drug product labeling final rule. For these reasons, the agency believes that the numbers of affected products in the

different categories discussed in the collection of information in the final rule are little changed. Accordingly, the agency is listing the same number of respondents, annual frequency per response, and total annual responses in this notice.

The agency believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries already since the final rule was issued in 1999. The agency's experience with these inquiries made to the agency is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hours per inquiry. Second, the agency issued a draft guidance for industry entitled "Labeling Over-the-Counter Human Drug Products; Updating Labeling in ANDA's" (66 FR 11174, February 22, 2001), which included a number of labeling examples to assist holders of ANDAs for OTC drug products and manufacturers of reference listed drugs for the ANDAs to implement the new OTC drug product labeling regulation. This guidance should have reduced some of the hours per response and total hours for some NDA and ANDA holders. However, the agency is not currently able to estimate how much the time has been reduced. Accordingly, the agency is listing the same hours per response and total hours in this notice as appeared in the final rule.

In the **Federal Register** of September 27, 2001 (66 FR 49388), the agency requested comments on the proposed collections of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.66	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

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

Dated: _____

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