

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01 N-03981

DMB

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

**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 of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of OTC drug products.

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

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. 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.

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**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:** 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: (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.

### **Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling**

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 the 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 of the labeling requirements (21 CFR 201.66) requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d). 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 stock keeping 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 3.4 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 § 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 May 16, 2001, compliance date by 1 year to May 16, 2002 (with a corresponding extension of the May 16, 2002, compliance date for products with annual sales of less than \$25,000 to May 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 hour 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.

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

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

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	66,642
201.66(c) and (d)	61	a.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
<b>Total</b>					<b>120,578</b>

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

Dated: 9-21-01  
September 21, 2001.

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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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