

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	<i>Monique Oliver</i>

[Docket No. 00N-1575]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Nutrition Labeling; Declaration of Caloric Amounts and Serving Sizes for Breath Mints

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.

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: Wendy Taylor, Desk Officer for FDA.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Nutrition Labeling; Declaration of Caloric Amounts and Serving Sizes for Breath Mints—
21 CFR 101.9(b) and (c)(1) (OMB Control Number 0910–0364)—Extension**

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)) requires that the label or labeling of a food bear nutrition information, including information on: (1) The serving size and number of servings per container, and (2) the number of calories present in a serving of the food. Under FDA's nutrition labeling regulations in § 101.9(d)(3) (21 CFR 101.9(d)(3)), the nutrition facts panel of the food label must disclose the serving size of the food product and the number of servings in each package. Under § 101.9(c)(1), the nutrition facts panel must disclose the number of calories present in a serving of the food.

In the **Federal Register** of December 30, 1997 (62 FR 67775), FDA published a proposed rule to amend the nutrition labeling regulations by changing the label serving size for the product category "Hard candies, breath mints" to one unit. FDA proposed this change in response to a petition to provide a serving size for breath mints that more accurately reflects the amount customarily consumed per eating occasion. In a related issue, FDA also proposed to: (1) Modify the rounding rules for calories to allow the declaration of caloric amounts of less than 5 calories on the nutrition label, and (2) require that the number of calories declared on the nutrition label of a food product be consistent with any claims about caloric content that are made in its labeling. As a result of this proposed rule, manufacturers, packers, or distributors who make labeling claims that their products contain between 1 and 5 calories would be required to change the declaration of the amount of calories on the nutrition label. In addition, manufacturers of small breath mints would be required, under § 101.9(b), to change the serving size and, under § 101.9(c) and (d), to modify the amounts and daily values for nutrients listed in the nutrition label for their products. The proposal included 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.

In the **Federal Register** of December 5, 2000 (65 FR 75940), the agency requested comments on the proposed collection 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 ²	Total Annual Responses	Hours per Response	Total Operating Costs	Total Hours
101.9(b) and (c)(1)	4	7.5	30	1	\$15,000	30

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

² Due to an inadvertent error, the "Annual Frequency per Response" column was omitted from the notice issued in the FEDERAL REGISTER of December 5, 2000 (65 FR 75940). Table 1 of this document contains the inserted column.

The proposed modification of the rules for the declaration of the amount of calories and the proposed change of the label serving size on the nutrition facts panel would result in a one-time burden created by the need for firms to revise their labels. In addition to changing the statement of calories and the serving sizes, firms would have to recalculate the number of servings per container and any nutrient amounts and daily values affected by the change in serving size. Of those breath mints for which FDA has information regarding the size of the product, there are 4 firms producing 5 brands of small breath mints, or approximately 30 distinct small breath mint labels. These are the only firms that would be affected by this proposed rule. FDA estimates that these firms would require an average of 1 hour per label to comply with the requirements of a final rule based on this proposal. For breath mint products, the average administrative, redesign, and inventory disposal costs for a labeling change of this type, with a 1-year compliance period, would result in a one-time operating cost of \$500 per label, or a total estimated operating cost of \$15,000.

Dated: February 22, 2001

William Hubbard

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

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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