

A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01-4852 Filed 2-27-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-1852]

Agency Information Collection Activities; Announcement of OMB Approval; Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Postmarketing Studies for Approved Human Drug and Licensed Biological Products; Status Reports" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of October 30, 2000 (65 FR 64607), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0433. The approval expires on February 29, 2004. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 March 30, 2001.

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: