that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product;
5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier, such as plant number, and last date of inspection; and
6. Assurance that the firm or individual representing the firm and submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of section 1001 of Title 18, United States Code. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Shell eggs	10	1	10	0.25	2.5
Dairy	100	1	100	0.25	25
Game meat and meat products	10	1	10	0.25	2.5
Animal casings	15	1	15	0.25	3.75
Gelatin	6	1	6	0.25	1.5
Total					35.25

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

The estimated number of respondents is based on the volume of exports and responses received to date. The estimated number of yearly responses has decreased from the estimate in FDA's previous notice seeking comment for this collection of information (63 FR 29738, June 1, 1998) because the actual number of responses has been decreasing. Companies do not need to reapply unless they have a compliance problem. An estimate for processors that export gelatin also has been added because these processors are now being included in the listing process.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (THIRD PARTY DISCLOSURE)[1]

Respondents	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Trade association	15	1	15	8	120
State	50	1	50	8	400
Total					520

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

The burden estimated for the trade associations assumes the trade associations will disseminate FDA's information request through mass mailings to their membership or publish it in their trade magazine or newsletter. The burden estimated for State authorities assumes dissemination of information to the processors or dissemination of information about processors to FDA.

Dated: February 22, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4851 Filed 2–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1440]

Agency Information Collection Activities; Announcement of OMB Approval; User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''User Fee Cover Sheet'' 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 December 5, 2000 (65 FR 75942), 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 0910–0297. 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.

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

BILLING CODE 4160–01–S

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.

[FR Doc. 01–4853 Filed 2–27–01; 8:45 am]

BILLING CODE 4160–01–S

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: