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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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 K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–4849 Filed 2–27–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01F–0026]

Avecia, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 1B4726) proposing that the food additive regulations be amended to provide for the safe use of poly(hexamethylenebiguanide) hydrochloride as a preservative for food-contact paper coating formulations.

FOR FURTHER INFORMATION CONTACT: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 23, 2001 (66 FR 7498), FDA announced that a food additive petition (FAP 1B4726) had been filed by Avecia, Inc., 1405 Foulk Rd., P.O. Box 15457, Wilmington, DE 19850–5457. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of poly(hexamethylenebiguanide) hydrochloride as a preservative for food-contact paper coating formulations. Avecia, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: February 14, 2001.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–4848 Filed 2–27–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission; Notice of Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of March 2001.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: March 7, 2001; 9:00 a.m.–3:00 p.m.

Place: Parklawn Building, Conference Rooms G and H, 5600 Fishers Lane, Rockville, Maryland 20857.

The meeting is open to the public.

The full Commission will meet on Wednesday, March 7, from 9:00 a.m. to 3:00 p.m. Agenda items will include, but not be limited to: (1) A presentation from Petitioners Attorneys' Perspective; (2) a discussion by the Chief Special Master of the U.S. Court of Federal Claims regarding its Alternative Dispute Resolution General Order #11, and soliciting comments from the public on the development of a new website; (3) and a report on the Institute of Medicine's Immunization Safety Review Committee. Updates from the Division of Vaccine Injury Compensation, Department of Justice, the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on March 7, 2001. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–2124. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in the Conference Room at the Parklawn Building, 5600 Fishers Lane, Conference Rooms G and H, Rockville, Maryland