

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 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. 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.

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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