Federal Register on August 28, 1990 (55 FR 35185).

In addition to the solicitation of written material through the Federal Register, a series of public meetings is being held to provide an opportunity for interested parties to contribute relevant information and comments concerning the particular guidelines under development.

A public meeting to address the guideline for the treatment of stage two and greater pressure ulcers will be held on April 9, 1992, as follows: Thursday, April 9, 1992, in Washington, DC, 8:30 a.m. to 11:30 a.m., Sheration Washington Hotel, 2660 Woodley Road at Connecticut Avenue, NW., Washington, DC 20008, Phone: 202–328–2000.

Background

The Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) enacted on December 19, 1989, added a new Title IX to the Public Health Service Act (the Act) (42 U.S.C. 299–299c–6), which established the Agency for Health Care Policy and Research (AHCPR) to enhance the quality, appropriateness, and effectiveness of health care services, and access to such services.

Section 911 of the Act (42 U.S.C. 299b) established within AHCPR, the Office of the Forum for Quality and Effectiveness in Health Care (the Forum). Through this office, AHCPR is arranging for the development and periodic review and updating of clinically relevant guidelines that may be used by physicians, educators, other health care practitioners, and consumers to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

Section 912 of the Act (42 U.S.C. 299b-1(d)) provides for the development of initial guidelines, standards, performance measures, and review criteria that:

1. Account for a significant portion of expenditures under the Medicare program, and have a significant variation in the frequency or the type of treatment provided; or

2. Otherwise meet the needs and priorities of the Medicare program.

Section 914 of the Act (42 U.S.C. 299b—3(a)) identifies factors to be considered in establishing priorities for guidelines, including the extent to which the guidelines would:

1. Improve methods of prevention, diagnosis, treatment, and clinical management, and thereby benefit a significant number of individuals;

2. Reduce clinically significant variations among clinicians in the particular services and procedures utilized in making diagnoses and providing treatments; and

3. Reduce clinically significant variations in the outcomes of health care services and procedures.

The following topics were selected in 1990 for guidelines development:

1. Management of Functional Impairment Due to Cataract in the Adult.
2. Diagnosis and Treatment of Benign Prostatic Hyperplasia.
3. Urinary Incontinence in Adults.
4. Prediction, Prevention, and Early Intervention of Pressure Ulcers.
5. Sickle Cell Disease.
6. Acute Pain Management: Operative or Medical Procedures and Trauma.
7. Diagnosis and Treatment of Depressed Outpatients in Primary Care Settings.

In 1991, the following additonal topics were selected for guidelines development by panels of experts and consumer representatives arranged for by AHCPR:

1. Management of Cancer-Related Pain.
2. Treatment of Stage II and Greater Pressure Ulcers.
3. HIV Positive Asymptomatic Patient: Evaluation and Early Intervention.
4. Low Back Problems.
5. Development of Quality Determinants of Mammography.
6. Screening for Alzheimer's and Related Dementias.

Also in 1991, three topics were selected for guidelines development by contractors, with assistance from panels of experts and consumer representatives:

1. Otitis Media in Children.
2. Diagnosis and Treatment of Heart Failure Secondary to Coronary Vascular Disease.
3. Post Stroke Rehabilitation.

Responsibilities of the expert panels and contractors, assisted by contract panels, include determination of the scope of the guidelines, assessment of the available scientific evidence and clinical consensus, and conducting peer review of drafts of the guidelines.

Thus far, public meetings of panels to solicit information and comments from interested parties have been held with respect to benign prostatic hyperplasia, depression, management of post-operative and cancer pain, pressure ulcers prevention, urinary incontinence, sickle cell disease, and cataracts.

Arrangements for the April 9 Public Meeting on Treatment of Stage Two and Greater Pressure Ulcers.

Representatives of organizations and other individuals are invited to provide relevant written comments and information and make a brief (5 minutes or less) oral statement to the panel. Mikalix and Company (M&C), the organization which provides logistical and technical support to the panels, is making the administrative arrangements for this public meeting on behalf of the panel. Individuals and representatives who would like to attend must register with M&C at the address set out below by March 20, 1992, and indicate whether they plan to make an oral statement. Those wishing to make oral statements and provide written comments and information should also submit copies of these to M&C by March 20. If more requests to make oral statements are received than can be accommodated between 8:30 a.m. and 11:30 a.m. on April 9, the chairperson will allocate speaking time in a manner which ensures, to the extent possible, that a range of views of health care professionals and providers, health care consumers, product manufacturers, and pharmaceutical manufacturers, is presented. Those who cannot be granted their requested speaking time because of time constraints can be assured that their written comments will be considered by the panel in developing the guideline.

Registration should be made with and written materials submitted to the following address: Mikalix and Company, Attn: Mary Ann Freshour, 404 Wyman Street, suite 375, Waltham, Massachusetts 02154–1210, Phone: 617–290–0090, Fax: 617–290–0180.

Dated: March 4, 1992.

J. Jarrett Clinton,

Administrator.

[FR Doc. 92–5506 Filed 3–9–92; 8:45 am]

BILLING CODE 4160-90-M

Centers for Disease Control

Advisory Committee for Energy Related Epidemiologic Research; Establishment

Pursuant to Federal Advisory Committee Act, 5 U.S.C. appendix 2, the Centers for Disease Control (CDC) announces the establishment by the Secretary of Health and Human Services (HHS), on February 29, 1992, of the following Federal advisory committee:

DESIGNATION: Advisory Committee for Energy-Related Epidemiologic Research.

SUPPLEMENTARY INFORMATION: The Secretary of Energy established an advisory committee to make recommendations on strengthening the

Department of Energy's (DOE) epidemiologic research activities. This distinguished committee recommended that DOE enter into a Memorandum of Understanding (MOU) with HHS to manage and conduct analytic epidemiologic research (studies which test hypotheses). The Secretary of Energy agreed with the Committee's recommendations and requested that HHS enter into an MOU for implementation. The MOU recommended the establishment of an Advisory Committee for Energy-Related Epidemiologic Research.

PURPOSE: The Advisory Committee for Energy-Related Epidemiologic Research will advise and make recommendations to the Secretary, HHS, the Assistant Secretary for Health, the Director, CDC, and the Administrator, Agency for Toxic Substances and Disease Registry, on establishment of a research agenda and the conduct of a research program pertaining to energy-related analytic epidemiologic studies. The Committee will take into consideration information and proposals provided by DOE, and advisory committee which will be established by DOE under the guidelines of the MOU, and other agencies and organizations, regarding the direction HHS should take in establishing the research agenda and in the development of a research plan.

Authority for this committee will expire February 29, 1994, unless the Secretary of HHS, with the concurrence of the Committee Management Secretariat, General Services Administration, formally determines that continuance is in the public interest.

Dated: March 4, 1992.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 92-5507 Filed 3-9-92; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 92F-0015]

GE Silicones; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that GE Silicones has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyoxyethylene-grafted polydimethylsiloxane as a flow-control agent in silicone coatings intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B4302) has been filed by GE Silicones, c/o Hyman, Phelps and McNamara, 1120 G St. NW., Washington, DC 20005. The petition proposes to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of polyoxyethylene-grafted polydimethylsiloxane as a flow-control agent in silicone coatings intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: February 27, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-5594 Filed 3-9-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 92F-0055]

Miles, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice

SUMMARY: The Food and Drug Administration (FDA) is announcing that Miles, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of dimethyl dicarbonate as a yeast inhibitor in ready-to-drink tea beverages.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9515.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A4310) has been filed by Miles, Inc., Mobay Rd., Pittsburg, PA 15205-9741. The petition proposes to amend the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFRF 172.133) to provide for the safe use of dimethyl dicarbonate as a yeast inhibitor in ready-to-drink tea beverages.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: February 27, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-5595 Filed 3-9-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90P-0193]

Cottage Cheese Deviating From Identity Standard; Extension and Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension and amendment of a temporary permit issued to the The Kroger Co., to market test a product designated as "nonfat cottage cheese" the deviates from the U.S. standards of identity for cottage cheese (21 CFR 133.128), dry curd cottage cheese (21 CFR 133.129), and lowfat cottage cheese (21 CFR 133.131). These actions will allow the permit holder to continue experimental market testing of the product while the agency takes action on a petition to establish a new standard of identity for "nonfat cottage cheese."

DATES: The new expiration date of the permit will be either the effective date of a final rule which may result from the petition, or 30 days after termination of such rulemaking.

FOR FURTHER INFORMATION CONTACT: Margaret E. Cole, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC, 20204, 202-485-0343.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), a temporary permit was issued to The Kroger Co., 1014 Vine St., Cincinnati, OH 45202–1100, to market test a product designated as "nonfat cottage cheese" that deviates from the U.S. standards of identity for cottage cheese (21 CFR 133.128), dry curd cottage cheese (21 CFR 133.129), and lowfat cottage cheese (21 CFR 133.131). Notice of issuance of the temporary permit to The Kroger Co., was published in the **Federal Register** of August 9, 1990 (55 FR 32473). The temporary permit was amended August 23, 1991 (56 FR 41850) to include additional container sizes and to change the milkfat content of the test product to less than 0.4 percent.

The Kroger Co. has requested that the temporary permit be extended so that the market test period can continue while agency action on a petition to establish a new standard of identity for "nonfat cottage cheese" proceeds. The permit holder also requested that their existing temporary permit be amended as follows: (1) to provide for market testing of 4,535,147 kilograms (kg) (10,000,000 pounds (lb)) of the test product in 1992 and 5,442,177 kg (12,000,000 lb) in 1993 and (2) to include a 425-gram (15-ounce) container size of nonfat cottage cheese not specified in the firm's previous temporary marketing permit (August 9, 1990, 55 FR 32473), as amended (August 23, 1991, 56 FR 41850).

The Kroger Co., in accordance with 21 CFR 130.17(i), submitted a petition from the Milk Industry Foundation (MIF) to establish a new standard of identity for "nonfat cottage cheese" at the same time the application for an extension and amendment was submitted. FDA is inviting interested persons to participate in the market test under the conditions that apply to The Kroger Co., including the labeling requirements and the amounts of test product to be distributed, except that the designated area of distribution shall not apply.

Any person who wishes to participate in the extended market test must motify, in writing, the Acting Director, Division of Food Chemistry and Technology (HFF–410), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The notification must include the amount of test product to be distributed, the area of distribution, and the labeling that will be used for the test product (i.e., a label for each size of container and each brand of product to be test marketed).

Therefore, under the provision of 21 CFR 130.17(i), FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule which may result from the petition, or 30 days after termination of such relemaking. All other conditions and terms of this permit remain the same.

Dated: February 24, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–5514 Filed 3–9–92; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 92G–0008]

Opta Food Ingredients, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the law offices of Patton, Boggs & Blow, on behalf of Opta Food Ingredients, Inc., have filed a petition (GRASP 2G0386) proposing that 4-hexylresorcinol be affirmed as generally recognized as safe (GRAS) as a direct human food ingredient for the prevention of melanosis in shrimp.

DATES: Written comments by May 11, 1992.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9519.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409 (21 U.S.C. 321(s), 348)) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that the law offices of Patton, Boggs & Blow, on behalf of Opta Food Ingredients, Inc., have filed a petition (GRASP 2G0386) proposing that 4-hexylresorcinol be affirmed as GRAS as a direct human food ingredient for the prevention of melanosis in shrimp. The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in §§ 170.30 and 170.35 (21 CFR 170.30 and 170.35) is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Interested persons may, on or before May 11, 1992, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS for the proposed use. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 27, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–5512 Filed 3–9–92; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 91E–0491]

Determination of Regulatory Review Period for Purposes of Patent Extension; Pravachol®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Pravachol® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–