participating in the selection process to consult with the others in selecting a single member representing industry interests for the panel within 60 days after receipt of the letter. If no individual is selected within 60 days, the agency will select the nonvoting member representing industry interests.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–17601 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on certain device panels of the Medical Devices Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Product Radiation Safety Standards Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and those that will or may occur through June 30, 1999.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: All nominations and curricula vitae for the device panels should be sent to Nancy J. Pluhowski, Office of Device Evaluation (HFZ–400), CDRH, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

All nominations and curricula vitae for health professionals, industry representatives, and government representatives for the Device Good Manufacturing Practice Advisory Committee should be sent to Sharon Kalokerinos, CDRH (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

All nominations and curricula vitae for government and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee should be sent to Orhan Suleiman, CDRH (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850.

All nominations and curricula vitae for general public representatives for the Device Good Manufacturing Practice Advisory Committee and the Technical Electronic Product Radiation Safety Standards Committee should be sent to Annette Funn, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kathleen L. Walker, Center for Devices and Radiological Health (HFZ–17), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1283, ext. 114.

SUPPLEMENTARY INFORMATION: FDA is requesting nominations of voting members for vacancies listed below.

1. *Circulatory System Devices Panel*: Two vacancies occurring June 30, 1999; interventional cardiologists, electrophysiologists, invasive (vascular) radiologists, vascular and cardiothoracic surgeons, and cardiologists with special interest in congestive heart failure.

2. *Clinical Chemistry and Clinical Toxicology Devices Panel*: One vacancy occurring February 28, 1999; doctors of medicine or philosophy with experience in clinical chemistry, clinical toxicology, clinical pathology, clinical laboratory medicine, or oncology.

3. *Dental Products Panel*: Three vacancies immediately, one vacancy occurring October 31, 1998; dentists who have expertise in the areas of lasers, endosseous implants, temporomandibular joint implants, dental materials and/or endodontics; or experts in bone physiology relative to the oral and maxillofacial area.

4. *Ear, Nose, and Throat Devices Panel*: One vacancy occurring October 31, 1998; audiologists, otolaryngologists, neurophysiologist, statisticians, or electrical or biomedical engineers.

5. *General Hospital and Personal Use Devices Panel*: Three vacancies immediately, one vacancy occurring December 31, 1998; internists, pediatricians, neonatologists, gerontologists, nurses, biomedical engineers or microbiologists/infection control practitioners or experts.

6. *Hematology and Pathology Devices Panel*: Two vacancies occurring February 28, 1999; cytopathologists and histopathologists; hematologists (blood banking, coagulation and hemostasis); molecular biologists (nucleic acid amplification techniques), and hematopathologists (oncology).

7. *Immunology Devices Panel*: One vacancy immediately, one vacancy occurring February 28, 1999; persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, human genetics testing or clinical laboratory medicine.

8. *Microbiology Devices Panel*: Three vacancies immediately, one vacancy occurring February 28, 1999; infectious disease clinicians; clinical microbiologists with expertise in antimicrobial and antimycobacterial susceptibility testing, chemotherapy and in vitro diagnostic (IVD) applications; clinical virologists with expertise in clinical diagnosis and IVD assays; clinical oncologists experienced with antitumor resistance and susceptibility; and molecular biologists.

9. *Obstetrics and Gynecology Devices Panel*: Two vacancies occurring January 31, 1999; experts in reproductive endocrinology, endoscopy, electrosurgery, laser surgery, assisted reproductive technologies, and contraception; biostatisticians and engineers with experience in obstetrics/gynecology devices; urogynecologists; experts in breast care; and experts in gynecology in the older patient.

10. *Orthopaedic and Rehabilitation Devices Panel*: Two vacancies occurring August 31, 1998; orthopedic surgeons experienced with prosthetic ligament devices, joint implants, or spinal instrumentation; physical therapists experienced in spinal cord injuries, neurophysiology, electrotherapy, and joint biomechanics; rheumatologists; or biomedical engineers.

11. *Radiological Devices Panel*: Two vacancies occurring January 31, 1999; physicians and scientists with expertise in nuclear medicine, diagnostic or therapeutic radiology, mammography, thermography, transillumination, hyperthermia cancer therapy, bone densitometry, magnetic resonance, computed tomography, or ultrasound.

12. *Device Good Manufacturing Practice Advisory Committee*: Four vacancies immediately, one government representative, one health professional, one industry representative, and one general public representative; five

vacancies occurring May 31, 1999; two government representatives, one health professional, one industry representative, and one general public representative.

13. *Technical Electronic Product Radiation Safety Standards Committee*: Five vacancies immediately, two government representatives, one industry representative, and two general public representatives; five vacancies occurring December 31, 1998, one government representative, three industry representatives, and one general public representative.

Functions

Medical Devices Panels

The functions of the panels are to: (1) Review and evaluate data on the safety and effectiveness of marketed and investigational devices and make recommendations for their regulation; (2) advise the Commissioner of Food and Drugs regarding recommended classification or reclassification of these devices into one of three regulatory categories; (3) advise on any possible risks to health associated with the use of devices; (4) advise on formulation of product development protocols; (5) review premarket approval applications for medical devices; (6) review guidelines and guidance documents; (7) recommend exemption to certain devices from the application of portions of the Federal Food, Drug, and Cosmetic Act (the act); (8) advise on the necessity to ban a device; (9) respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices; and (10) make recommendations on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.

The Dental Products Panel also functions at times as a dental drug panel. The functions of the drug panel are to: (1) Evaluate and recommend whether various prescription drug products should be changed to over-the-counter status; and (2) evaluate data and make recommendations concerning the approval of new dental drug products for human use.

Device Good Manufacturing Practice Advisory Committee

The functions of the committee are to review proposed regulations for promulgation regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The committee also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

Section 520 of the act (21 U.S.C. 360(j)), as amended, provides that the Device Good Manufacturing Practice Advisory Committee shall be composed of nine members as follows: Three of the members shall be appointed from persons who are officers or employees of any Federal, State, or local government, two shall be representatives of interests of the device manufacturing industry, two shall be representatives of the interests of physicians and other health professionals, and two shall be representatives of the interests of the general public.

Technical Electronic Product Radiation Safety Standards Committee

The function of the committee is to provide advice and consultation on the technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation from such products. The committee may recommend electronic product radiation safety standards for consideration.

Section 534(f) of the act (21 U.S.C. 360kk(f)), as amended by the Safe Medical Devices Act of 1990, provides that the Technical Electronic Product Radiation Safety Standards Committee include five members from governmental agencies, including State or Federal Governments, five members from the affected industries, and five members from the general public, of which at least one shall be a representative of organized labor.

Qualifications

Medical Device Panels

Persons nominated for membership on the panels shall have adequately diversified experience appropriate to the work of the panel in such fields as clinical and administrative medicine, engineering, biological and physical sciences, statistics, and other related professions. The nature of specialized training and experience necessary to qualify the nominee as an expert suitable for appointment may include experience in medical practice, teaching, and/or research relevant to the field of activity of the panel. The particular needs at this time for each panel are shown above. The term of office is up to 4 years, depending on the appointment date.

Device Good Manufacturing Practice Advisory Committee

Persons nominated for membership as a government representative or health professional should have knowledge of or expertise in any one or more of the following areas: Quality assurance concerning the design, manufacture, and use of medical devices. To be eligible for selection as a representative of the general public or industry, nominees should possess appropriate qualifications to understand and contribute to the committee's work. The particular needs are shown above. The term of office is up to 4 years, depending on the appointment date.

Technical Electronic Product Radiation Safety Standards Committee

Persons nominated must be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety. The particular needs are shown above. The term of office is up to 4 years, depending on the appointment date.

Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on one or more of the advisory panels or advisory committees. Self-nominations are also accepted. Nominations shall include a complete curriculum vitae of each nominee, current business address and telephone number, and shall state that the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

Consumer/General Public Representatives

Any interested person may nominate one or more qualified persons as a member of a particular advisory committee or panel to represent consumer interests as identified in this notice. To be eligible for selection, the applicant's experience and/or education will be evaluated against Federal civil service criteria for the position to which the person will be appointed.

Selection of members representing consumer interests is conducted through procedures which include use of a consortium of consumer organizations which has the responsibility for recommending candidates for the agency's selection. Candidates should possess appropriate qualifications to understand and contribute to the committee's work.

Nominations shall include a complete curriculum vitae of each nominee and shall state the the nominee is aware of the nomination, is willing to serve as a member, and appears to have no conflict of interest that would preclude membership. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory committee or in any advisory committee. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: June 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–17603 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92F–0443]

Dow Corning Corp.; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Dow Corning Corp. to indicate that the petitioner has also proposed that the food additive regulations be amended to provide for the safe use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 12, 1993 (58 FR 8290), FDA announced that a petition (FAP 3B4346) had been filed by Dow Corning Corp., P.O. Box 994, Midland, MI 48686–0994, proposing to amend § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300), § 175.320 *Resinous and polymeric coatings for polyolefin films* (21 CFR 175.320), and § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst. The petition also proposed that the food additive regulations be amended to provide for the safe use of 3,5-dimethyl-1-hexyne-3-ol, 1-ethynylcyclohexene, bis(methoxymethyl)ethyl maleate and methylvinyl cyclosiloxane as optional polymerization inhibitors. Additionally, the petition proposed that the regulations be amended to provide for the safe use of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one mixture, optionally containing magnesium nitrate, as an antimicrobial agent for emulsion-based silicone coating formulations.

Subsequent to publication of the filing notice, the petitioner amended the petition to request the use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

Therefore, FDA is amending the filing notice of February 12, 1993, to indicate that the petitioner requests that the food additive regulations be amended to provide for the safe use of tetramethyltetravinylcyclotetrasiloxane as an optional polymerization inhibitor in the manufacture of dimethylpolysiloxane coatings produced by cross-linking a vinyl-containing dimethylpolysiloxane with methylhydrogen-containing polysiloxane and dimethylmethylhydrogen polysiloxane polymers using a platinum catalyst.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 11, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–17548 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0484]

Eastman Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Eastman Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of di-2-ethylhexylterephthalate as a component of closure- sealing gaskets for food containers.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

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 food additive petition (FAP 8B4593) has been filed by Eastman Chemical Co., P.O. Box 431, Kingsport, TN 37662. The petition proposes to amend the food additive regulations in § 177.1210 *Closures with sealing gaskets for food containers* (21 CFR 177.1210) to provide for the safe use of di-2-ethylhexyl terephthalate as a component of closure-sealing gaskets for food containers.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment