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

nor an environmental impact statement is required.

Dated: June 17, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–17547 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0195]

Agreement on Mutual Recognition Between the United States of America and the European Community; Third Party Review Program Under the Sectoral Annex on Medical Devices; Conformity Assessment Bodies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is identifying the process for designating Conformity Assessment Bodies (CAB's) under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA). The MRA was signed in London on May 18, 1998, but it has not entered into force. FDA has published a proposed rule on the parts of the MRA affecting FDA-regulated products. This notice announces the process for CAB's to become eligible for designation under the Sectoral Annex on Medical Devices (Medical Devices Annex). The availability of the draft guidance detailing the requirements for performing evaluations, training for CAB's, and content of evaluation reports by FDA is announced elsewhere in this issue of the **Federal Register**. Also announced elsewhere in this issue of the **Federal Register** is an emergency processing request for Office of Management and Budget review of the information collection provisions of this notice.

FOR FURTHER INFORMATION CONTACT:

Regarding the U.S./European Community MRA: John F. Stigi, Director, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, or FAX: 301–443–8818.

Regarding the process for being recognized to assess U.S. CAB's or for naming a recognized accreditor: Robert L. Gladhill, Conformity Assessment Systems Evaluation, National Institute of Standards and Technology, NN, 282 Gaithersburg, MD 20899, 301–975–4273, or FAX: 301–963–2871.

SUPPLEMENTARY INFORMATION:

I. Background

On June 20, 1997, the United States and the European Community (EC) completed negotiation of the MRA that covered a variety of product sectors, including telecommunication equipment, recreational craft, pharmaceuticals, and medical devices. The Medical Devices Annex applies only to medical devices manufactured for export to the United States or EC. The EC consists of the following member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. FDA issued a proposed rule on April 10, 1998 (63 FR 17744), to add a new section to its regulations setting out requirements through which FDA may normally endorse certain reports of conformity assessments. The Medical Device Annex applies to reports of quality system evaluations of all medical devices and premarket evaluations of selected medical devices provided by designated conformity assessment bodies.

Assuming the MRA enters into force and a final rule becomes effective, a 3-year transition period will start during which time both sides will engage in confidence building activities. After the 3-year transition period and the confidence building activities are successfully completed, the operational period will begin.

The MRA consists of a framework agreement and individual sectoral annexes (i.e., those product sectors covered by the MRA). The framework agreement covers the general aspects of the implementation of the agreement as well as the requirements governing the CAB's, such as designation, listing, suspension, and withdrawal.

Within the framework agreement there is a provision that FDA and EC Designating Authorities review the Medical Devices Annex. It is anticipated that aspects of the Medical Devices Annex will be modified by agreement of FDA and EC Designating Authority as laws and policies change. This provision was included because of FDA's concern during the negotiations that there could be a change in the status of the FDA Third Party Review Pilot Program for medical devices that would change the nature of the agreement.

Under the MRA, an EC CAB could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Similarly, a U.S. CAB could conduct quality system evaluations for all classes of devices and product type examinations and verifications for selected devices based on EC requirements. In addition, an alert system would be set up during the transition period and maintained thereafter by which FDA and regulatory authorities will notify each other when there is an immediate danger to public health. As part of that system, FDA and EC will notify each other of any confirmed problem reports, corrective actions, or recalls.

The MRA may: (1) Be an important means of facilitating movement of medical devices important to human health between the United States and EC, (2) enhance public health by allowing better use of scarce FDA resources, (3) enhance harmonization of U.S. and EC regulatory systems, and (4) permit FDA to better utilize its regulatory resources to focus on manufacturers located in other countries.

Under the MRA, both the United States and the EC may eventually be able to save resources by utilizing evaluations of manufacturers conducted by the other party, thereby saving overseas travel time and expense. However, CAB's will be required to participate in rigorous joint activities in order to demonstrate proficiency in conducting FDA and EC evaluations. Based on demonstrated proficiency during a 3-year transition period, both FDA and EC are expected to ''normally endorse'' evaluations conducted by the other party's CAB's, while reserving the final decision making to themselves and reserving the right to conduct their own evaluations should significant deficiencies be found in any reports.

II. Third Party Review Program

The Medical Devices Annex identifies legislation, regulations, and related procedures under which: (1) Products are regulated as medical devices by each party (i.e., FDA and the EC); (2) CAB's are designated and confirmed; and (3) evaluation reports are prepared. Assuming the MRA enters into force and a final rule becomes effective, FDA will be the Designating Authority for U.S. CAB's and the EC Regulatory Authorities will be the Designating Authority for EC CAB's. FDA intends to use the National Voluntary Conformity Assessment System Evaluation