

components of articles intended for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 8, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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: April 24, 1998.

**Laura M. Tarantino**,  
Acting Director, Office of Premarket  
Approval, Center for Food Safety and Applied  
Nutrition.

[FR Doc. 98-12169 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98F-0288]

#### Mitsui Chemicals, Inc.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Mitsui Chemicals, Inc., has filed a petition proposing that the food additive regulations be amended to expand the safe use of propylene/butene-1 copolymers containing greater than 15

but not more than 35 weight percent of polymer units derived from butene-1 for use in contact with food.

**DATES:** Written comments on the petitioner's environmental assessment by June 8, 1998.

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

#### 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:** 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 8B4590) has been filed by Mitsui Chemicals, Inc., c/o Keller & Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to expand the safe use of propylene/butene-1 copolymers containing greater than 15 but not more than 35 weight percent of polymer units derived from butene-1 for use in contact with food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 8, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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: April 24, 1998.

**Laura M. Tarantino**,  
Acting Director, Office of Premarket  
Approval, Center for Food Safety and Applied  
Nutrition.

[FR Doc. 98-12168 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 81G-0035]

#### Dairy Crest Food, Ltd.; Withdrawal of GRAS Affirmation 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 petition (GRASP 1G0273) proposing that the use of immobilized lactase composite is generally recognized as safe (GRAS) for use in the production of low-lactose whey.

#### FOR FURTHER INFORMATION CONTACT:

Valerie M. Davis, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3181.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of March 3, 1981 (46 FR 14970), FDA announced that a petition (GRASP 1G0273) had been filed by Corning Glass Works, Corning, NY. The petition proposed affirmation that the use of immobilized lactase composite is GRAS for producing low-lactose whey.

In a letter dated January 8, 1988, a law firm, on behalf of Corning Glass Works, informed the agency that sponsorship of the petition was transferred to Dairy Crest Food, Ltd., Dairy Crest House, Portsmouth Rd., Surbiton, Surrey KT6 5QL, England.

On May 29, 1996, the agency contacted the attorney of record for Dairy Crest Foods, Ltd., and inquired whether Dairy Crest Foods, Ltd., was still pursuing the petition, given that the last communication from the petitioner was 5 years previously. This inquiry was prompted by an agency initiative to remove those petitions that are no longer being pursued from FDA's petition inventory. No response was received.

By letter of May 29, 1997, FDA again contacted Dairy Crest Food, Ltd.'s,

attorney to reiterate the agency's initiative to remove from its pending petition inventory those petitions that are no longer being pursued by the petitioner. In that letter, the agency stated that if Dairy Crest Foods, Ltd., wished to pursue the petition, the agency would continue to work on it. However, if Dairy Crest Food, Ltd., did not wish to pursue the petition, the agency requested that Dairy Crest Food, Ltd., withdraw the petition without prejudice to a future filing. FDA asked that the petitioner inform the agency of its decision within 30 days of the date of the letter; the agency added that failure to respond within that time would be considered approval to withdraw the petition. As of this date, Dairy Crest Food, Ltd., has not responded to FDA in any way. Therefore, the agency is announcing that it considers this petition to be withdrawn by the firm, without prejudice to a future filing (21 CFR 171.7).

Dated: April 27, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-12055 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

**Name of Committee:** Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

**General Function of the Committee:** To provide advice and recommendations to the agency on FDA regulatory issues.

**Date and Time:** The meeting will be held on June 5, 1998, 9 a.m. to 5 p.m.

**Location:** Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

**Contact Person:** Sara M. Thornton, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2053, or

FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12396, or the World Wide Web (WWW) at <http://www.fda.gov>. Please call the Information Line for up-to-date information on this meeting.

**Agenda:** The committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for an excimer laser for the correction of myopia using laser in-situ keratomileusis. FDA staff will present to the committee the clinical requirements section of the proposed International Standards Organization standard for ophthalmic viscosurgical devices.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 29, 1998. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., and between approximately 1 p.m. and 1:30 p.m. An additional 30-minute time period will be given for public comment at the end of the panel discussion on the PMA. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 29, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 30, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98-12170 Filed 5-6-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-2567-A]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and

Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

#### Type of Information Collection

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Statement of Deficiencies and Plan of Correction and Supporting Regulations in 42 CFR 486.301-.325; **Form No.:** HCFA-2567-A (OMB# 0938-0391); **Use:** This Paperwork package provides information regarding deficiencies for Organ Procurement Organizations (OPO) as well as deficiencies noted during periodic facility and laboratory certification surveys. This information is used to make decisions concerning OPO redesignation, certification/recertification of health care facilities participating in the Medicare/Medicaid Programs, and laboratories regulated by the Clinical Laboratory Improvement Amendments; **Frequency:** Biennially and Annually; **Affected Public:** Business or other for-profit, not-for-profit institutions, Federal Government, and State, local or tribal government; **Number of Respondents:** 49,200; **Total Annual Responses:** 98,400; **Total Annual Hours:** 196,800.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards, Attention: Louis Blank, Room C2-26-17, 7500 Security