SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *N*-methyl-*N*-(1-oxo-9-octadecenyl)glycine as a corrosion inhibitor for lubricants with incidental food contact.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4124) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) be amended to provide for the safe use of *N*-methyl-*N*-(1-oxy-9-octadecenyl)glycine as a corrosion inhibitor for lubricants with the incidental food contact.

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: January 13, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–1713 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0426]

Huels AG; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Huels AG has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3-aminomethyl-3,5,5-trimethylcyclohexylamine as a cross-linking agent for use in epoxy resins complying with the indirect food additive regulations.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4118) has been filed by Huels AG, P.O. Box 1320, D–4370 Marl, Federal Republic of Germany, proposing that § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) be amended to provide for the safe use of 3-aminomethyl-3,5,5-trimethylcyclohexylamine as a cross-linking agent for use in epoxy resins complying with § 175.300(b)(3)(viii).

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: January 13, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–1714 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 85F–0082]

Ecolab, Inc.; Amended Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by Economics Laboratory, Inc. (now Ecolab, Inc.), to provide for the safe use of decanoic acid, octanoic acid, a mixture of 1-octanesulfonic acid and 1-octanesulfonic-2-sulfinic acid, and the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine as components of sanitizing solutions to be used on food-processing equipment and other food-contact articles. This notice makes clear that the sanitizing solution also contains lactic acid, phosphoric acid, and FD&C Yellow No. 5, and that the mixture of 1-octanesulfonic acid and 1-octanesulfonic-2-sulfinic acid also contains 1,2-octanedisulfonic acid.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 8, 1985 (46 FR 9521), FDA announced that a petition (FAP 5H3842) had been filed by Economics Laboratory, Inc., St. Paul, MN 55102 (the name and address of the company have been changed to Ecolab, Inc., Ecolab Center, St. Paul, MN 55102), proposing that the food additive regulations be amended to provide for the safe use of decanoic acid, octanoic acid, a mixture of 1-octanesulfonic acid and 1-octanesulfonic-2-sulfinic acid, (OSA mixture), and the condensate of four moles of poly(oxyethylene)poly(oxypropylene) block copolymers with one mole of ethylenediamine as components of sanitizing solutions to be used on food processing equipment and other food-contact articles. Subsequently, Ecolab, Inc., amended the petition and indicated the presence of 1,2-octanedisulfonic acid in the OSA mixture.

This notice makes clear that this ingredient is in the sanitizing solution and that this solution also contains FD&C Yellow No. 5, lactic acid, and phosphoric acid, components which were also not listed in the original notice of filing.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an environmental assessment under 21 CFR 25.31a(a).

Dated: January 13, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–1819 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88G–0388]

Fuji Oil Co., Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Fuji Oil Co., Ltd., has filed a petition (GRASP 8G0348) proposing to affirm that cocoa butter substitutes from safflower oil and sunflower oil are generally recognized as safe (GRAS) for use as direct human food ingredients.

DATE: Comments by March 27, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that Fuji Oil Co., Ltd., 6–1, Hachiman-cho, Minami-ku, Osaka 542 Japan, has filed a petition (GRASP 8G0348) proposing that cocoa butter substitutes from safflower oil and sunflower oil be affirmed as GRAS for use as direct human food ingredients. 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 March 27 1989. 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 substances are, or are 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: January 13, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–1717 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0428]

Takeda Chemical Industries, Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a petition (GRASP 8G0342) has been filed on behalf of Takeda Chemical Industries, Ltd., proposing to affirm that urease enzyme derived from *Lactobacillus fermentum* be affirmed as generally recognized as safe (GRAS) as a direct human food ingredient.

DATE: Comments by March 27, 1989.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 8G0342) has been filed on behalf of Takeda Chemical Industries, Ltd., c/o 1730 Rhode Island Ave. NW., Washington, DC 20076, proposing that urease enzyme derived from nonpathogenic and nontoxigenic *Lactobacillus fermentum* be affirmed as GRAS for use as a direct human food ingredient to prevent the development of ethyl carbamate in the alcoholic beverage Sake. The GRAS petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the requirements outlined in 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 March 27, 1989, 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: January 13, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–1718 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

Advisory Committee; Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Circulatory System Devices Panel

Date, time, and place. February 6, 1989, 8:30 a.m., Rm. 703A–727A, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 10:30 a.m.; open committee discussion, 10:30 a.m. to 2:30 p.m.; closed committee deliberations, 2:30 p.m. to 4 p.m.; Keith Lusted, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7594.

General function of the committee. The committee reviews and evaluates

available data on the safety and effectiveness of medical devices currently in use and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 30, 1989, 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 required to make their comments.

Open committee discussion. The committee will discuss an industry presentation of the use of doppler ultrasound in the characterization of prosthetic heart valves, and premarket approval applications (PMA's) for a pulse generator system and a patent ductus arteriosus occluder.

Closed committee deliberations. The committee will discuss trade secret or confidential commercial information regarding the PMA's listed above. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (Subpart C of 21 CFR Part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR Part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

Details on the agenda, questions to be addressed by the committee, and a current list of committee members are available from the contact person before and after the meeting. Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, Rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94–409), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information on the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770–776 (5 U.S.C. App. I)), and FDA's regulations (21 CFR Part 14) on advisory committees.

Dated: January 13, 1989.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 89–1710 Filed 1–23–89; 4:00 pm]

BILLING CODE 4160–01–M