approval of a new animal drug application (NADA) held by The Dow Chemical Co. The NADA provides for use of a Type A medicated article containing zoalene and roxarsone for making Type C medicated chicken feeds. The firm requested withdrawal of approval.

EFFECTIVE DATE: February 6, 1989.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3183.

SUPPLEMENTARY INFORMATION: The Dow Chemical Co., P.O. Box 1706, Midland, MI 48640, is the sponsor of NADA 36–682 which was originally approved by letter of August 28, 1967. The NADA provides for use of the type the Type A medicated article Zoamix® N which contains 25 percent zoalene and 10 percent roxarsone in making Type C medicated chicken feeds. The feeds are used as an aid for the prevention and control of caecal and intestinal coccidiosis and as an aid in stimulating growth, increasing feed efficiency, and for improving pigmentation.

In a letter dated May 16, 1988, the sponsor requested withdrawal of approval of the NADA and waived opportunity for hearing because the product is no longer being marketed.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 36–682 and all supplements thereto is hereby withdrawn, effective February 6, 1989.

Dated: Jan 18, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89–1716 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 81D–0319]

Collection of Platelets, Pheresis; Availability of Revised Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guideline prepared by the Center for Biologics Evaluation and Research for the collection of Platelets, Pheresis prepared by automated procedures using a currently approved instrument. The guideline is intended for use by blood collecting facilities that prepare platelets by this method.

ADDRESSES: The guideline may be seen at and comments submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. Requests for a copy of the revised guideline to the Biologics Information Staff (HFB–205), Building 29, Room B–16, 8800 Rockville Pike, Bethesda, MD 20892, 301–496–9508.

FOR FURTHER INFORMATION CONTACT: Joseph Fratantoni, Center for Biologics Evaluation and Research (HFB–480), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–496–2577.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 27, 1981 (46 FR 52430), FDA announced the availability of a guideline for the collection of Platelets, Pheresis prepared by mechanical pheresis using a currently approved instrument. Platelets, Pheresis is a licensed biological product that may be prepared using automated equipment in an approved blood banking facility. FDA made the guideline available to recommend criteria for donor safety and to help ensure that final platelet products were safe and effective. In the **Federal Register** of April 2, 1984 (49 FR 13079), FDA announced the availability of a draft revised guideline intended to replace the original guideline made available in 1981. The draft revised guideline differed from the original guideline in several ways, including a revised standard for Platelets, Pheresis, a provision for donation of platelets for a specific recipient, and removal of some recommended platelet testing and processing procedures during donation periods.

In the 1984 notice, FDA also announced a 2-day public workshop to discuss issues concerning platelets. Public comments received on the draft revised guideline were discussed during the public workshop held on May 22 and 23, 1984. The draft revised guideline has been revised further as a result of comments received. Since 1984 FDA has approved new instrumentation and separation techniques, and has implemented additional testing for assuring the safety of blood products. These changes are reflected in the revised guideline.

In addition, the current revised guideline differs from the April 1984 draft revised guideline with respect to recommendations such as the donor deferral time interval after aspirin ingestion, an increase in the maximum number of platelet collections from a donor in any 1 year, and revised labeling.

FDA is making available the revised guideline under 21 CFR 10.90(b), which provides for the use of guidelines to outline procedures or standards of general applicability that are acceptable to FDA for a subject matter that falls within the laws administered by FDA. Although guidelines are not a legal requirement, a person may be assured that in following an agency guideline the procedures followed and standards used will be acceptable to FDA. A person may also choose to use alternative procedures or standards for which there is scientific rationale even though they are not provided for in a guideline. A person who chooses to use procedures or standards different from procedures or standards in a guideline may discuss the matter further with the agency to prevent an expenditure of resources for work that FDA may later determine to be unacceptable.

Copies of the revised guideline have been distributed to blood bank establishments and plasmapheresis centers that have pending or approved license applications to prepare Platelets, Pheresis using pheresis instruments for which the Center for Biologics Evaluation and Research has acceptable data.

Requests for a copy of the revised guideline should be sent to the Biologics Information Staff (address above).

Interested persons may submit to the Dockets Management Branch written comments on the revised guideline. 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.

Dated: January 18, 1989.

John M. Taylor

Associate Commissioner for Regulatory Affairs.

[FR Doc. 89–1715 Filed 1–25–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88F–0442]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

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