FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11:00 a.m., Monday, October 26, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed 1999 Federal Reserve Board employee salary structure adjustments and merit program.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: October 16, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–28268 Filed 10–16–98; 3:40 pm]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0894]

Ecolab Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ecolab Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent to wash or assist in the lye peeling of fruits and vegetables that are not raw agricultural commodities without the requirement of a potable water rinse following treatment.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3072.

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 8A4622) has been filed by Ecolab Inc., 370 North Wabasha St., St. Paul, MN 55102. The petition proposes to amend the food additive regulations in § 173.315 *Chemicals used in washing or to assist in the peeling of fruits and vegetables* (21 CFR 173.315) to provide for the safe use of a mixture of peroxyacetic acid, hydrogen peroxide, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent to wash or assist in the lye peeling of fruits and vegetables that are not raw agricultural commodities without the requirement of a potable water rinse following treatment.

The agency has determined under 21 CFR 25.32(q) 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: October 1, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–27994 Filed 10–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G–0413]

Vulcan Chemical Technologies, Inc.; 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 3G0020) proposing to affirm that the use of chlorine dioxide is generally recognized as safe (GRAS) in the treatment of potable water and the washing of fruits and vegetables.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 23, 1973 (38 FR 7578), FDA announced that a petition (GRASP 3G0020) had been filed by Olin Corp., 120 Long Ridge Rd., Stamford, CT 06904. This petition proposed that the use of chlorine dioxide in the treatment of potable water and the washing of fruits and vegetables be affirmed as GRAS. In June 1992, Vulcan Chemicals (now Vulcan Chemical Technologies, Inc.), 1902 Channel Dr., West Sacramento, CA 95691–3477, acquired the rights to this petition.

In the **Federal Register** of July 20, 1998 (63 FR 38746), FDA amended § 173.300 *Chlorine dioxide* (21 CFR 173.300) to provide for the use of chlorine dioxide to wash fruits and vegetables that are not raw agricultural commodities. This action was taken in response to a food additive petition (FAP 4A4415) that included uses requested in GRASP 3G0020. Thus, FDA requested that GRASP 3G0020 be withdrawn. Vulcan Chemical Technologies, Inc. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: October 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–28059 Filed 10–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97E–0269]

Determination of Regulatory Review Period for Purposes of Patent Extension; Aldara™ (5,238,944)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Aldara™ (5,238,944) and is publishing

this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Aldara™ (5,238,944) (imiquimod). Aldara™ (5,238,944) (U.S. Patent No. 5,238,944) is indicated for the treatment of external genital and perianal warts/condyloma acuminata in adults. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Aldara™ (5,238,944) from Riker Laboratories, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 22, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Aldara™ (5,238,944) represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Aldara™ (5,238,944) is 3,471 days. Of this time, 3,254 days occurred during the testing phase of the regulatory review period, 217 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* August 30, 1987. The applicant claims September 1, 1987, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was August 30, 1987, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* July 26, 1996. The applicant claims July 25, 1996, as the date the new drug application (NDA) for Aldara™ (5,238,944) (NDA 20–723) was initially submitted. However, FDA records indicate that NDA 20–723 was submitted on July 26, 1996.

3. *The date the application was approved:* February 27, 1997. FDA has verified the applicant's claim that NDA 20–723 was approved on February 27, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 187 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before December 21, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before April 19, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–27995 Filed 10–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of November 1998.

NAME: National Advisory Council on Migrant Health.

DATE & TIME: Thursday, November 12, 1998 at 9:00 a.m. to Friday, November 13, 1998 at 1:00 p.m.

PLACE: Sheraton Springfield, 1 Monarch Place, Springfield, MA 01144, 413/781–1010 (phone) or 413/734–3249 (fax). he meeting is open to the public.

AGENDA: This will be a meeting of the Council. The agenda includes an overview of general Council business activities and priorities. Topics of discussion will include the State Children's Health Insurance Program, Worker Protection Standards, the collaboration possibilities with other migrant health advocate organizations, and the 1998 NACMH Recommendations. In addition, the