

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 8, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00-14945 Filed 6-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Committee on Immunization Practices (ACIP).

Times and Dates: 8:30 a.m.-6:30 p.m., June 21, 2000. 8 a.m.-4:30 p.m., June 22, 2000.

Place: Four Points Hotel by Sheraton, 1850 Cotillion Drive, Atlanta, Georgia 30338.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with advising the Director, CDC, on the appropriate uses of immunizing agents. In addition, under 42 U.S.C. § 1396s, the Committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines.

Matters To Be Discussed: The agenda will include a discussion on the ACIP policies and procedures; ACIP recommendations for the pneumococcal conjugate vaccine; vaccine additive: aluminum update; vaccine additive: thimerosal; vaccines and autism; bioterrorism working group; general recommendations; anaphylaxis after MMR due to gelatin; progress report on vaccine identification standards initiative; status of high-speed needle-free jet injectors for mass vaccination campaigns; update on Geneva meeting on rotavirus vaccination; Vaccines for Children program update; adult working group: pneumococcal polysaccharide update; CDC/FDA report on two dose schedule for hepatitis B for adolescent; update on influenza vaccine supply; Global Alliance for Vaccines and Immunization: progress in supporting global immunization programs and introduction of new vaccines; Nabi an

update from the Food and Drug Administration; update from the National Center for Infectious Diseases; update from the National Immunization Program; update from the Vaccine Injury Compensation Program; update from the National Vaccine Program. Other matters of relevance among the committee's objectives may be discussed.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information:

Gloria A. Kovach, Program Analyst, Epidemiology and Surveillance Division, National Immunization Program, CDC, 1600 Clifton Road, NE, m/s E61, Atlanta, Georgia 30333. Telephone 404/639-8096.

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Dated: June 8, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N-0412]

Rajaram K. Matkari; Conviction Reversal; Final Order Terminating Debarment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (the act), terminating the debarment of Rajaram K. Matkari, 1304 Riverglen Way, Berthoud, CO 80513. FDA is issuing this order because the U.S. District Court for the District of Maryland issued a Writ of Error Coram Nobis, reversing Mr. Matkari's conviction and Mr. Matkari applied for termination of his debarment on this basis.

EFFECTIVE DATE: June 13, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug

Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 20, 1993 (58 FR 54156), Rajaram K. Matkari was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). The debarment was based on FDA's finding that Mr. Matkari was convicted of a felony under Federal law for conduct relating to the development or approval of a drug product, or otherwise relating to the regulation of a drug product (section 306(a)(2)(A) and (a)(2)(B) of the act). Mr. Matkari, the former Vice President for Regulatory Affairs and Product Development of Pharmaceutical Basics, Inc. (PBI), pled guilty to and was sentenced on July 28, 1989, for giving an unlawful gratuity, a felony offense under 18 U.S.C. 201(c)(1)(A). The basis for this conviction was Mr. Matkari's payment of approximately \$2,000 to an FDA chemistry review branch chief who was responsible for supervising the chemists who reviewed PBI's applications to determine whether those applications met certain statutory standards for approval.

On February 22, 2000, the U.S. District Court for the District of Maryland issued an order granting Mr. Matkari's petition for a Writ of Error Coram Nobis in his criminal case. A copy of the court's order is available in Docket No. 92N-0412. By this order, the court reversed Mr. Matkari's conviction. On April 18, 2000, Mr. Matkari petitioned for termination of debarment under section 306(d)(3)(B)(i) of the act, as amended by the Generic Drug Enforcement Act. Section 306(d)(3)(B)(i) of the act states that "If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) * * * is reversed, the Secretary shall withdraw the order of debarment."

Accordingly, the Senior Associate Commissioner for Policy, Planning, and Legislation, under section 306(d)(3)(B)(i) of the act and under authority delegated to him (21 CFR 5.20), is issuing this order withdrawing the order of permanent debarment of Rajaram K. Matkari, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. Rajaram K. Matkari's debarment is terminated

effective June 13, 2000, (section 306(d)(3)(B)(i) of the act).

Dated: June 6, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00-14806 Filed 6-12-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F-1332]

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, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses.

DATES: Submit written comments on the petitioner's environmental assessment by July 13, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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: 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 0A4720) has been filed by Ecolab, Inc., Ecolab Center, 370 Wabasha St., St. Paul, MN 55102. The petition proposes to amend the food additive regulations in 21 CFR part 173 (21 CFR part 173) to provide for the safe use of a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid as an antimicrobial agent on red meat carcasses.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued 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 submit to the Dockets Management Branch written comments by July 13, 2000. 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 Dockets Management Branch 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: May 30, 2000.

Alan M. Rulis,

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

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BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastrointestinal Drugs 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: Gastrointestinal Drugs Advisory Committee.

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

Date and Time: The meeting will be held on June 26 and 27, 2000, 8:30 a.m. to 5:30 p.m.

Location: Marriott Washington Center, Ballrooms A through E, 9751 Washington Blvd., Gaithersburg, MD.

Contact Person: Thomas H. Perez, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6758, e-mail at PerezT@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12538. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 26, 2000, the committee will discuss new drug application (NDA) 21-200, Zelmac™ (tegaserod), Novartis Pharmaceuticals Corp., for the treatment of abdominal pain and discomfort, bloating and altered bowel function in patients with irritable bowel syndrome who have predominant symptoms of pain, discomfort, and constipation. On June 27, 2000, the committee will discuss risk management of post-marketing adverse events associated with NDA 21-107, Lotronex™ (alosetron) Glaxo Wellcome.

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 June 19, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 19, 2000, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the June 26 and 27, 2000, Gastrointestinal Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Gastrointestinal Drugs Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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