

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic 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: Dermatologic and Ophthalmic 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 November 4, 2002, from 8:30 a.m. to 5:30 p.m. and November 5, 2002, from 8 a.m. to 1 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both the days, committee will make recommendations for the development of a proposed draft guidance concerning the development of products for mild to moderate acne vulgaris. Issues to be considered include: (1) The evidence for effectiveness; (2) appropriate outcome measures and their analyses; (3) possible acceptable indications such as inflammatory, noninflammatory or just mild to moderate acne vulgaris; and (4) means for conveying evidence for effectiveness in the label to enhance its usefulness for clinicians and patients. Time will be included in the agenda for the pharmaceutical industry to present their views on the development of the draft guidance. Please register to present (see *Contact Person*) by October 18, 2002.

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 October 18, 2002. Oral

presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m. on November 4, 2002, and between approximately 8:15 a.m. and 8:45 a.m. on November 5, 2002. Time allotted for each presentation may be limited. If you wish to make a brief statement during the open public hearing, please contact the Executive Secretary (see *Contact Person*), by October 18, 2002.

You will be asked to submit a brief summary of your planned statement and provide information on how we may contact you before the meeting.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Karen Templeton-Somers at least 7 days in advance of the meeting.

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

Dated: October 9, 2002.

Linda Arey Skladany,

Senior Associate Commissioner for External Relations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Infant Formula Subcommittee of the Food 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: Infant Formula Subcommittee of the Food Advisory Committee.

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

Date and Time: The meeting will be held on November 18, 2002, from 8 a.m. to 6 p.m. and November 19, 2002, from 8 a.m. to 5 p.m.

Location: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Conference Center, 4700 River Rd., Riverdale, MD, 301-734-8010.

Contact Person: Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS-800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1756, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The meeting's purpose is to discuss the scientific issues and principles involved in assessing and evaluating whether a "new" infant formula supports normal physical growth in infants when consumed as a sole source of nutrition. This is the second meeting of a series of advisory committee meetings to discuss the scientific issues involved in evaluating whether a new infant formula supports normal physical growth.

FDA will post information relating to this meeting on the Internet at <http://www.cfsan.fda.gov/~lrd/vidtel.html>.

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 November 1, 2002. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on November 19, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 13, 2002, 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.

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FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jeanne E. Latham at least 7 days in advance of the meeting.

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