Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 430.18.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: January 5, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–445 Filed 1–7–05; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on February 14, 2005, from 2 p.m. to 6 p.m. and on February 15, 2005, from 8 a.m. to 4:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14C–06) Rockville, MD 20857, 301–827–6687, e-mail: *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up-to-date information on this meeting.

Agenda: On Monday, February 14, 2005, the committee will discuss an agency report on Adverse Event Reporting, as mandated in Section 17 of the Best Pharmaceuticals for Children Act (BPCA), for LOTENSIN (benazepril), BREVIBLOC (esmolol), MALARONE (atovaquone/proguanil), VIRACEPT (nelfinavir), XENICAL (orlistat), and GLUCOVANCE (glyburide/metformin). The committee will also be asked to advise the agency on how to improve the process and content of the adverse event reviews and reporting as mandated by BPCA.

On Tuesday, February 15, 2005, the committee will discuss risk evaluation, labeling, risk communication, and dissemination of information on potential cancer risk among pediatric patients treated for atopic dermatitis with topical dermatological immunosuppressants.

The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) docket Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* (click on the year 2005 and scroll down to PAC meetings).

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 February 7, 2005. Oral presentations from the public will be scheduled on Monday, February 14, 2005, between approximately 4 p.m. and 4:30 p.m. and on Tuesday, February 15, 2005, between approximately 12 noon and 12:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by February 7, 2005, 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.

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 notify Jan Johannessen 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: December 30, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 05–382 Filed 1–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000P–1378]

Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients.'' The guidance recommends content for a labeling statement for cosmetic products containing alpha hydroxy acids (AHAs) as ingredients. This action was prompted by a citizen petition filed by the Cosmetic, Toiletry, and Fragrance Association, which requested that FDA issue a regulation establishing labeling requirements relating to sun protection with use of cosmetic products containing AHAs.

DATES: You may submit written or electronic comments on the guidance document at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Office of Cosmetics and Colors, Center for Food Safety and Applied Nutrition (HFS–100), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835. Include a self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Julie N. Barrows, Center for Food Safety and Applied Nutrition (HFS–125), Food and