



Memorandum of Meeting

Date: September 23, 2004

Place: Vermont Ave. Building, Rm. 1149
Washington, DC

Participants: Food and Drug Administration
Linda M. Katz, M.D., M.P.H., Director, Office of Cosmetics and Colors (OCAC)
Catherine J. Bailey, Director, Division of Cosmetics and Compliance (DCC), OCAC
John Lipnicki, Team Leader, Compliance and Regulations Team (CRT), DCC, OCAC
Julie Barrows, Ph.D., Consumer Safety Officer, CRT, DCC, OCAC
Irene Chan, General Attorney, Office of the General Counsel

Environmental Working Group
Arianne Callender, EWG General Counsel (delayed arrival)
Jane Houlihan, Vice President for Research
Richard Wiles, Senior Vice President
Tim Kropp, Senior Scientist/Toxicologist

Subject: Citizen Petition from Environmental Working Group (Docket No. 2004P-0266/CP1)

The meeting was held at the request of the Environmental Working Group (EWG) to discuss its June 14, 2004, petition to the Food and Drug Administration (FDA). The visitors submitted an agenda which included a request for a description of OCAC's activities, EWG's investigation of ingredients in 7,500 cosmetic products, issues raised in the petition, and EWG's findings with regard to the interpretation of safety by the Cosmetic Ingredient Review (CIR).

FDA participants provided EWG with information on OCAC's organizational structure and a list of OCAC's current priority projects which are part of the 2004 program priorities for FDA's Center for Food Safety and Applied Nutrition (CFSAN). Dr. Katz commented that FDA is actively working on its response to the petition.

EWG participants stated two main concerns. First, they stated that there is no clear safety standard for most ingredients in cosmetics and that they believe that cosmetic ingredients should have a safety standard similar to the safety standard for food and color additives. Second, they stated that the agency does not have the ability to obtain data from cosmetic manufacturers.

EWG participants also stated that they disagree with some recommendations for use of cosmetic ingredients, based on an evaluation of safety, that were published by the CIR. Dr. Katz noted that the FDA uses many sources, including the CIR, for assessing the safety of cosmetic ingredients. Other sources include the CFSAN Adverse Event Reporting System (CAERS), published scientific literature, data provided directly to FDA by other government agencies as well as the cosmetic industry, FDA research, and other information submitted to the agency for review.

2004P-0266

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