DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 3 2005

E. Edward Kavanaugh
The Cosmetic, Toiletry and Fragrance Association
1101 17th Street, NW
Suite 300
Washington, D.C. 20036-4702

Dear Mr. Kavanaugh:

As you know, the Food and Drug Administration (FDA) is responsible for the regulation and oversight of cosmetics in the United States. I want to assure you that FDA takes these responsibilities seriously and we will be continuing our efforts to ensure that the products we regulate, including cosmetics, are safe. In December 2004, the Center for Food Safety and Applied Nutrition released its 2005 Program Priorities. These priorities include two items specifically aimed at ensuring that cosmetic products being marketed in the United States remain safe.

The first of these priorities addresses a citizen petition received from the Environmental Working Group (EWG) alleging that cosmetic products are currently being marketed in the United States with ingredients that have been determined by the Cosmetic Ingredient Review Expert Panel (CIR) to be unsafe, or to have insufficient data for a determination of safety, or to fall outside the qualifications for safe use. We are also aware that this issue has been given substantial publicity in California, in connection with consideration of state legislation to impose additional requirements relating to cosmetic safety. We are preparing a response to the EWG citizen petition. Additionally, you should know that FDA intends to consider taking compliance action, where appropriate, regarding cosmetic products that contain ingredients that we determine have not been shown to be safe, based on findings of the CIR Expert Panel and other sources of information available to the Agency, but that are not currently labeled with the warning statement ("Warning – The safety of this product has not been determined.") required under 21 CFR 740.10. In the past we have taken appropriate action based in part on the CIR Expert Panel determination of safety.

FDA regards the CIR Expert Panel determinations an important element in ensuring the safety of the cosmetic supply in the United States. Indeed, we have provided a Liaison Representative to the Expert Panel since approximately 1980 and plan to continue to provide a representative.

The second 2005 Program Priority related specifically to cosmetics is the development of draft guidance to implement 21 CFR 740.10. The guidance is intended to provide information to manufacturers on determining the adequacy of safety substantiation of

ingredients in cosmetic products and on determining when the 21 CFR 740.10 warning statement would be necessary.

Again, let me reassure you that I am committed to taking the appropriate actions and steps to ensuring that the cosmetic products currently being marketed in the United States remain safe.

I hope the information I have provided you regarding our plans is helpful. I encourage you to keep your members informed of the efforts FDA is currently taking related to regulation and oversight of cosmetic products. The Agency will be providing outreach and information on our efforts to all of our stakeholders, including the cosmetic industry.

I look forward to continuing to work with you and the cosmetic industry as we move forward with our cosmetic safety priorities. If you have questions, please do not hesitate to contact me.

Sincerely,

Robert E. Brackett, Ph.D.
Director
Center for Food Safety
and Applied Nutrition