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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

May 20, 2003

E. EDWARD KAVANAUGH
P R E S I D E N T

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

Re: Docket No. 03D-0092:
Cosmetic Security Preventive Measures Guidance

Dear Sir or Madam:

These Comments are filed on behalf of the members of The Cosmetic, Toiletry, and Fragrance Association ("CTFA")¹ in response to the draft Cosmetic Security Preventive Measure Guidance for cosmetics processors and transporters that was announced in the *Federal Register* on March 21, 2003 (68 Fed. Reg. 13932).

CTFA members have always taken their responsibility to ensure the safety of their products very seriously. This includes not only the safety of the ingredients and finished products themselves, but also the need to protect these products from any kind of tampering that could threaten the safety of the consumer or those involved in the manufacturing or distribution process. The industry's focus on protection of the products has included addressing the issues raised by the Agency's draft Guidance.

The terrorist attacks on the United States on September 11, 2001, and subsequent incidents in several locations involving tampering with the mail have only served to heighten the industry's vigilance against any tampering with our products or unauthorized intervention in our manufacturing or distribution systems.

To assist our members in reviewing steps taken to protect their products, CTFA prepared "Product Security and Tampering Incident Guidelines" which were

¹ CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. Founded in 1894, CTFA has approximately 600 members involved in manufacturing and distributing personal care products throughout the United States.

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distributed to our membership in December 2001. This document was prepared after consultations with key FDA personnel knowledgeable in security and emergency response issues, and the CTFA Guidelines have been shared with those same personnel.

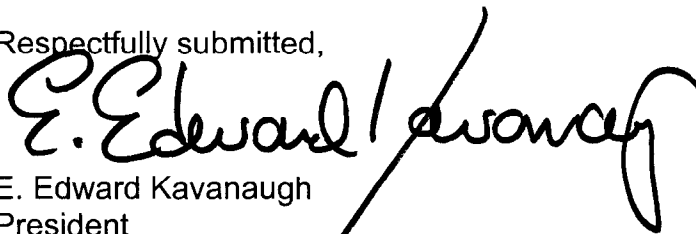
After reviewing FDA's draft Guidance, we believe that the Agency has provided guidelines for the industry that are remarkably consistent with the CTFA Guidelines and which provide sound advice for companies to consider when they review their product security procedures. CTFA supports these efforts by FDA to encourage all FDA-regulated industries to remain attentive to product security issues.

We would like to underscore one very important aspect of a guidance of this type recognized by FDA in the section of the draft entitled "Limitations." Because of the diversity of the industry, all of the Guidance may not be applicable to every company, and each company must have the flexibility to tailor its response to the Guidance to fit its individual situation. The appropriate action will vary depending on the size of the company, types of products, how it manages research and development, manufacturing, and distribution, and many other issues.

Therefore, it is very important to emphasize the statement by the Agency that neither the Guidance nor the examples cited therein should be considered minimum standards that must be met by every company. It is equally important that FDA's field staff be advised against a literal interpretation of this Guidance during inspections, evaluation of imports or other interactions with the industry. The Guidance will be most useful to both the Agency and the industry in reaching the common goal of product security if it is viewed as a flexible tool for identifying issues that may need to be addressed to ensure product security and safety.

CTFA looks forward to continuing to work with FDA on this very important issue. Please contact us if you need any clarification or further information.

Respectfully submitted,

A handwritten signature in black ink that reads "E. Edward Kavanaugh". The signature is written in a cursive style with a long, sweeping underline that extends to the right.

E. Edward Kavanaugh
President

cc: Joseph A. Levitt (HFS-001)
Linda M. Katz, M.D. (HFS-100)
John E. Kvenberg (HFS-600)
Donald W. Kraemer (HFS-400)