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E. Edward Kavanaugh
P r e s i d e n t

August 9, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Program Priorities (FY2005) in the Center for Food
Safety and Applied Nutrition; Request for Comments;
Docket No. 1998N-0359

Dear Sir or Madam:

The following comments are submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") in response to the request for comments on Program Priorities for the Center for Food Safety and Applied Nutrition (CFSAN) for Fiscal Year 2005 (October 1, 2004 to September 30, 2005). 69 Fed. Reg. 35380 (June 24, 2004). Our comments are focused on the priorities for CFSAN related to its responsibilities for cosmetic regulation.

CTFA is the national trade association representing the cosmetic industry. Founded in 1894, CTFA has almost 600 members involved in formulating, manufacturing, distributing and marketing personal care products. Our members are responsible for manufacturing or distributing the vast majority of personal care products sold in the United States.

The cosmetic industry takes pride in its strong safety record and long history of self-regulation. Our self-regulatory programs such as the Cosmetic Ingredient Review (CIR) are not only very effective – they save scarce government resources. Working with CFSAN and its Office of Cosmetics and Colors, CTFA has supported many self-regulatory programs that have helped assure that the consumer will benefit from a wide variety of safe products. FDA's support for and participation in these programs has been a critical factor in assuring their success.

As in the past, CTFA will continue to urge Congress to maintain adequate funding for cosmetic regulation in CFSAN. We strongly believe that a fully-funded, credible cosmetic regulatory program is necessary. We are concerned that there appears to be a reduction in the resources available to the Office of

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Cosmetics and Colors in progress, and urge that the Office be maintained at its current strength or greater in order that it can complete its priorities in a timely manner.

Because of our belief in the importance of a strong cosmetic regulatory program, we urge FDA to make it a very high priority to work with the industry to assure the continued success of CIR and our other self-regulatory programs.

The following are CTFA's recommendations for the CFSAN 2005 Priorities affecting cosmetic products:

I. Complete a Guidance for Labeling of Products Containing Alpha Hydroxy Acids

This should remain an "A List" Priority.

As we did in commenting on FY2004 priorities, we must again express a concern that some projects that have been accorded high priority are taking a long time to complete. The Guidance for Labeling of alpha hydroxy acid products is a prime example of such delays. The Guidance was published in draft form in December 2002 in response to a June 2000 Citizen Petition by CTFA that requested FDA to take the same action through a regulation. The final Guidance has still not been published, even though it has been listed as an "A List" Priority in past years. We urge the Agency to complete this matter as quickly as possible so that industry members can address the issue of sun sensitivity on AHA products, where appropriate, in a manner consistent with FDA Guidance.

In completing its work on this Guidance, we again urge FDA to consider CTFA's comments asking the Agency to exempt products that contain AHA's but do not have the same exfoliating characteristics for various reasons such as de minimus concentrations, the fact that the AHA ingredient is included in a product to serve a technical and non-exfoliating function, the product is used on areas of the body not exposed to the sun, or, at a very minimum, in cases where the manufacturer is in possession of competent and reliable data demonstrating that the product does not increase sun sensitivity.

II. Remove the 2004 "B List" Priority to Develop a Guidance for Cosmetic Labeling

As part of its 2004 Priorities, CFSAN included on its "B List" a "Guidance for Cosmetic Labeling: Develop a plan to establish criteria for cosmetic claims, implement the Inter-Center agreement concerning cosmetic products making drug claims through review of labeling, and conduct regulatory follow-up." We

urge the Center to reconsider this priority and remove it from its 2005 list for the following reasons.

While we do not disagree that FDA has enforcement authority to deal with a situation where a manufacturer is making drug claims for a cosmetic product and to review labeling to determine whether any such claims merit action by the Agency, we do not believe it is either advisable or legally-justified to establish a guidance attempting to define what words constitute cosmetic claims or drug claims. We infer that such action is contemplated from the wording of the 2004 priority.

It is clear from long-standing legal precedent and recent actions by the Agency that the proper regulatory classification ("drug" or "cosmetic") is determined by the "intended use" of the product. The intended use is, in turn, determined from the claims made for the product by the manufacturer or distributor. In making this determination, words or phrases cannot be viewed in the abstract, but must be analyzed in the context of the surrounding material promoting the product.

Thus, we do not believe it would be constructive for FDA to propose a guidance which attempts to classify words or phrases in the abstract as cosmetic or drug terms. There will always be situations where a term that may be considered a drug claim in one context can be properly qualified so as to be considered a cosmetic claim by consumers in another context. For example, the word "treatment" can be used in very different ways. A "beauty treatment" is clearly a cosmetic claim, but a "disease treatment" is a drug claim.

In any such case where claims affecting product regulatory classification are at issue, it is the understanding of the "reasonable consumer" that will determine how a claim will be perceived. This is impossible to ascertain in the abstract, since the consumer will be influenced by the context in which he/she sees or hears specific words or phrases.

Classification of words or phrases as "drug" or "cosmetic" claims without taking into account every possible context in which such words or phrases may appear – a virtual impossibility - is almost certain to result in an arbitrary barrier to truthful claims about a cosmetic product. FDA has made it one of its broader goals to remove arbitrary barriers to truthful information about FDA-regulated products, an action dictated by both recent court decisions and good policy. We believe development of a Guidance for claims would be a step back from this important effort.

We urge FDA to abandon any attempt to establish guidelines for claims as outlined in its 2004 CFSAN Priorities.

III. Complete the Review and Listing of Carbon Black as a Color Additive for Cosmetic Use

On July 28, 2004, FDA published an amendment to the color additive regulations providing for the safe use of D&C Black No. 2 in response to a petition filed by CTFA (69 Fed. Reg. 44927). This has been a long-standing issue before the Agency, and we appreciate and strongly support FDA's action to make this color available to cosmetic manufacturers.

IV. Allow the Industry to Use Appropriate Ingredient Nomenclature to Facilitate International Harmonization

This is a repeated request for CFSAN to give greater attention to an important priority that will benefit the consumer and enhance international harmonization of labeling nomenclature. For a more complete exposition of each of the following recommendations, please see CTFA's comments to the Docket on program priorities for FY 2004.

a. Colour Index ("CI") Numbers

The Colour Index or "CI" number is recognized throughout most of the world as an appropriate way to label color additives. There are currently over 80 countries requiring the CI number for cosmetic labeling purposes, while only one, the United States, requires FDA nomenclature.

Designation of colorants on cosmetic product labels using the international CI number was begun in Europe in 1993 to lessen the confusion of providing parochial nomenclature in many different languages. Additionally, it was recognized that the CI number system could be used in place of more complicated chemical identifiers for the colorants, as the CI numbers are applied to specific colorants with known specifications. Both CTFA and Colipa, the European Cosmetic, Toiletry and Perfumery Association, have previously requested that FDA recognize the CI nomenclature, but no action has been taken on these requests at this time.

In a December 2003 report on U.S. barriers to trade and investment in the Pharmaceuticals and Cosmetics section, the European Commission notes, "To date no progress has been made on the use of Colour Index numbers for ingredient labeling to identify colours contained in a product although a petition was submitted by industry several years ago to allow these numbers to be used in the U.S. since this system is applied in the EU and in most of the countries around the world." And in Canada, the recently published rules for ingredient

labeling will recognize the use of the CI number for colorant labeling, but will require the FDA nomenclature, if used, to be translated into French, therefore requiring additional work and labeling for U.S. companies wanting to market a product with labeling harmonized for the U.S. and Canada.

While FDA has requested information to review before acting on this industry request, and CTFA intends to pursue developing the information requested, we believe it would be helpful for FDA to make the acceptance of CI numbers for cosmetic product labeling for colorants an FY 2005 "A List" Priority. We believe the current issue is easily resolved with no risks to the consumer and minimal regulatory burden to the Agency. CTFA believes that FDA's recognition of this nomenclature system can be accomplished through recognition by the Director of the Office of Cosmetics and Colors, and that no formal rulemaking is necessary.

b. Botanicals

Latin genus and species names are recognized throughout the world as the most specific form of nomenclature for botanicals. English "common" names are frequently not specific as to species, are confused by the public among differing genera, and are frequently only regionally applied. Additionally, the same genus and species may be known by different common names. The industry has moved to address the concern that use of common names for labeling botanical ingredients on cosmetics could be deceptive to English speaking users, and incomprehensible for an international nomenclature system, by providing genus and species names for botanical ingredients.

In 1994, a thorough review of the nomenclature of botanical ingredients revealed that a patchwork of common names, genera names and genus and species names had been adopted over the years. In an effort to provide more consistent and understandable nomenclature, the 6th Edition of the *International Cosmetic Ingredient Dictionary* (1995) added the genus and species name to each botanical as a parenthetical. In addition, new botanicals were named by the genus and species method. This process continued through the 7th Edition of the *Dictionary* in 1997.

Also in 1995, CTFA began presentations to the dermatology community on the use of the new botanical nomenclature and the reasons for moving to the genus and species designations. An explanation of the changes was sent to each member of the American Academy of Dermatology and printed in the *Cosmetic Industry On Call*, a joint publication of the Academy and CTFA that is sent to each member of the Academy.

With the publication of the 8th Edition of the *Dictionary* in 2000, the final phase of the change over to genus and species designation began with the change in order of presentation from common name with Latin genus and species in parentheses to Latin genus and species with the common name in parentheses. Additionally, where the previous common name had actually been a genus or species name (Acorus for Acorus Calamus), or where it did not appear in any scientific or medical publication indexed by the National Library of Medicine (Zeodary), or where confusing (Bedstraw), it was dropped as a parenthetical. A cross reference was also developed and provided in that edition of the *Dictionary*.

CTFA is willing to work with FDA to provide a cross reference for common names for botanicals for FDA to put on its website, and will also make the same available on its own website. To demonstrate the importance of this issue, however, we believe that FDA should make this a CFSAN FY 2005 "A List" Priority.

We believe this issue is easily resolved with no risk to the consumer and minimal regulatory burden to the Agency. CTFA believes that FDA's recognition can be accomplished by the Director of the Office of Cosmetics and Colors, and that no formal rulemaking is necessary.

V. Cosmetic Labeling: Develop a strategy for amending 701.3(c)(2) to update sources for naming cosmetic ingredients

This is an "A List" Priority for 2004, and we agree that it is an important goal to explore ways to more efficiently facilitate the use of new cosmetic ingredient nomenclature as it is developed. CTFA has in past years proposed an approach to amending current regulations to do this. We support the recognition of this as an "A List" Priority, recommend the same treatment in 2005, and stand ready to work with FDA in giving this effort high priority.

VI. Implement the WEB-based Voluntary Cosmetic Registration Program

This was an "A List" priority in 2003, but was not listed in 2004, possibly in the expectation that the necessary clearances for internet registration would be obtained before the end of FY 2004. Time seems to be running out for that to be accomplished in this Fiscal Year.

While we recognize the considerable effort by the Office of Cosmetics and Colors on this project, we are disappointed that implementation of a more efficient,

WEB-based system for the program has been delayed too long. We support any possible efforts by CFSAN to resolve the obstacles to beginning this system.

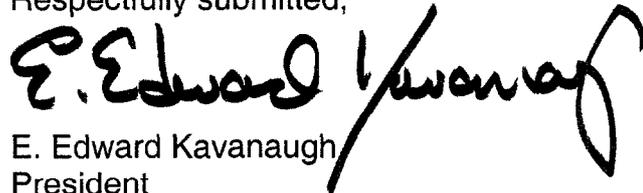
This is the foundation of an ongoing system that provides useful information on cosmetic manufacturing facilities and cosmetic ingredient usage to FDA. The WEB-based system will increase the flow of information, and will reduce the resource impact for both FDA and industry. The hard work has been done; high priority should be given to removing any obstacles to putting this system in place.

Conclusion

Once again, we must express significant frustration that many projects related to cosmetic regulation in CFSAN have not been completed within the time-lines established in previous CFSAN Priority documents. Nevertheless, we appreciate the opportunity to submit comments annually on the Center's priorities and pledge to work with the Center and the Office of Cosmetics and Colors to provide whatever information or other effort is necessary to expedite these matters to completion.

Please feel free to contact us if you have questions or need additional information on these or other matters before the Agency.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "E. Edward Kavanaugh". The signature is written in a cursive, somewhat stylized font. The first part of the signature, "E. Edward", is written in a more compact, blocky style, while "Kavanaugh" is written in a more flowing, cursive script. The signature is positioned above the printed name and title.

E. Edward Kavanaugh
President

cc: Robert E. Brackett, Ph.D.
Linda M. Katz, M.D.