C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION



January 31, 2003

E. EDWARD KAVANAUGH
PRESIDENT

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

Re: Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients
Docket No. 00P-1378

Dear Sir or Madam:

These comments are submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA")[1] in response to FDA's publication of "Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients." (67 Fed. Reg. 71577 [December 2, 2002]).

This action was taken by the Agency in response to a Citizen Petition filed by CTFA on June 29, 2000, requesting that FDA issue a regulation establishing sun alert labeling on AHA products. Specifically, CTFA requested that FDA issue a regulation establishing labeling requirements relating to sun protection for cosmetic products containing alpha hydroxy acids (hereafter "AHAs") that function as exfoliants. CTFA submitted that Petition to encourage the use of sunscreen in appropriate circumstances in conjunction with use of AHA products and for the period immediately following use.

[1] CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies involved in the sale or distribution of cosmetics, toiletries and fragrances throughout the world. CTFA represents the manufacturers or distributors of the vast majority of those products sold in the United States, including those products containing an alpha hydroxy acid as an ingredient. Approximately one-half of CTFA's members are manufacturers or distributors of finished personal care products. The other one-half are suppliers of goods or services to those manufacturers or distributors.

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The following labeling statement was requested for those products:

> "Sun Alert: Because this product may make your skin more sensitive to the sun, be certain you have adequate sunscreen protection while using this product and for a week after you discontinue use."

In response, FDA has published a Draft Guidance "...suggesting that the labeling of a cosmetic product that contains an AHA as an ingredient and that is intended for topical application to the skin or mucous membrane bear a statement that conveys the following information:

> "Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure while using this product and for a week afterwards."

**Overview and Summary of Recommendations**

CTFA supports the positive manner in which FDA has received its Petition and supports the goal of providing information about possible increased sun sensitivity to consumers of products containing AHAs in circumstances where this is appropriate. We believe that a Guidance is a reasonable and cost-effective way to accomplish this goal.

We do, however, strongly disagree with the failure of the Draft Guidance to exempt products containing AHA ingredients that are not intended to function as exfoliants and do not present an increased possibility of sun sensitivity or sunburn. In the discussion below, we have provided further evidence regarding the need to exempt these products in order to preserve the credibility and effectiveness of the "sunburn alert" statement. We have proposed criteria for when such a statement would be necessary. We believe the criteria proposed will address FDA's concerns.

We propose that the labeling recommended in the Guidance should apply only to cosmetic products

> (1) containing an AHA intended to be used as an exfoliant, and
>
> (2) intended for use on areas of the body normally susceptible to sunburn.

We propose that all AHA-containing products – even those that meet the above criteria – be exempted from the Guidance if:

- They contain no more than one percent (1%) AHA and have a pH of 3.5 or higher; or

- The manufacturer or distributor has competent and reliable scientific evidence demonstrating that such product (at any level of concentration and pH) does not cause increased likelihood of sunburn or sun sensitivity.

In addition, we suggest a modification in the suggested labeling language for the increasing number of AHA products that already contain sunscreens. This clarification is within both the letter and the spirit of the Draft Guidance. It simply eliminates the unnecessary message that consumers should use a sunscreen while using sunscreen containing products. The revised label for an AHA product with sunscreen would state:

> "Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure for a week after use of this product is stopped."

### A. CTFA Supports the Suggested FDA Label Statement for Appropriate Products That Do Not Contain Sunscreen

The suggested label statement differs in several significant respects from the statement proposed in CTFA's Citizen Petition. For example, it identifies the reason for the statement as the presence of AHA ingredients. It also urges consumers to limit sun exposure in addition to using a sunscreen and highlights the possibility of sunburn as well as increased sun sensitivity.

While there are merits to a shorter, more concise statement of the issue and recommended action for the consumer, we believe it is more important to finalize this action and encourage the inclusion of this important information on the label of appropriate AHA products. Therefore, we will support a label statement for appropriate AHA products that do not contain sunscreen. However, we urge FDA to reconsider whether it is necessary or prudent to recommend a label statement specifically referring to AHAs, particularly in light of the fact that the presence of an AHA ingredient does not always result in increased sun sensitivity or likelihood of sunburn.

We also urge the Agency to give serious consideration to the following issues.

### B. The Label Statement Should be Modified for Products that Contain a Sunscreen

In order to prevent consumer confusion and inappropriate action by consumers, we urge the Agency to clarify the suggested label language to deal with the

increasingly common situation of a product with an AHA ingredient that also contains sunscreen. In such a situation, it does not make sense to advise the consumer to use sunscreen while using the AHA product. Such a statement may confuse the consumer and cause inappropriate behavior such as disregard of directions that ignore the actual formulation of the product. The label statement for AHA products that also contain sunscreen should be shortened to address only the need to use a sunscreen for seven days after use of the AHA product is discontinued. The following language is suggested:

> Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen and limit sun exposure for a week after use of this product is stopped.

### C. Certain Products Containing an AHA Ingredient Should be Exempted from the Guidance

The FDA proposal states that, "The Draft Guidance represents the agency's current thinking of the labeling of topically applied cosmetic products that contain an AHA [alpha hydroxy acid] as an ingredient." Further it states that while the predominant AHAs in cosmetics are glycolic and lactic acids, others found include "citric acid, -hydroxyoctanoic acid [sic], and -hydroxydecanoic acid [sic]." Further, the Draft Guidance states that there is a possibility of sunburn from any AHA containing product, and therefore "FDA suggests a statement such as the 'Sunburn Alert' . . . for all AHA-containing products." (67 Fed. Reg. 71577-71579)

CTFA believes that the broad definition of cosmetics that would be subject to the Draft Guidance, "all AHA containing products," is inappropriate, because:

- only products that have used AHAs for their exfoliant properties, to remove the dead outer layer of the skin to make it appear more smooth and youthful, have been shown to result in an increased susceptibility to sunburn,

- non-exfoliant uses of AHAs would not result in a product that could be reasonably anticipated to cause increased susceptibility to sunburn,

- increased sun sensitivity can only be anticipated to occur when the concentration of AHA or the pH in a particular product exceed a certain threshold, and

- some cosmetic product categories, because of their very nature and intended use, could not be reasonably anticipated to cause increased susceptibility to sunburn.

### 1. The Guidance Should Apply Only to Products Intended to Function as an Exfoliant

An evaluation of the safety of glycolic and lactic acids and their common salts and simple esters was undertaken by the Cosmetic Ingredient Review beginning in 1994. During that evaluation, it was established that high concentrations of these acids (10% at pH 3.5) could increase the skin's sensitivity to the sun (Int. J. Tox., 17(1) p. 1-241). FDA also states in the Notice that it has received three complaints regarding AHA products that caused sunburn, a sign of that increased sun sensitivity, between 1992 and 2000. CTFA's Citizen Petition, cited in the Draft Guidance, recognized that the use of these ingredients as exfoliants could increase the skin's sensitivity to the sun, and proposed establishing labeling in regard to those uses.

The Draft Guidance reports that between 1992 and 2000, FDA personnel compiled a survey of labeling of skin treatment products containing AHAs from the Washington, DC, area, and found that such products used varying labeling statements, only about one-half of which mentioned exfoliation. It goes on to state that the evidence FDA has reviewed so far suggests the possibility of sunburn from any AHA-containing product, and "not merely products labeled for exfoliant use. Therefore, FDA suggests a statement such as the 'Sunburn Alert' be included in the labeling for all AHA-containing products."

AHAs can have various non-exfoliant uses in cosmetic products including: pH adjuster, chelating agent, fragrance ingredient, humectant, and skin conditioning agent – miscellaneous or occlusive (International Cosmetic Ingredient Dictionary and Handbook, ninth edition 2002, Pepe, R.C., *et al.* eds., The Cosmetic, Toiletry, and Fragrance Association, Washington, DC, "ICID"). One example of an AHA ingredient noted in the Draft Guidance that is not primarily used as an exfoliant is citric acid. Citric acid is used primarily for its ability to adjust pH in formulations. As one example, in an evaluation of 210 shampoos it was found that citric acid was used as the component for pH adjustment in108 products (Cosmetics & Toiletries, March 1985, p. 45, "C&T"). Among the products that use citric acid are antiperspirants and deodorants.

Even AHAs that are known to be primarily used as exfoliants, lactic acid and glycolic acid, are also used at times as pH adjusters (5 and 3 shampoo formulations, respectively, C&T). Such use could not be reasonably anticipated to cause increased susceptibility to sunburn. Therefore, AHAs that are present

for other functions, such as pH adjusting, should not be included in the Guidance. Only those products that have an ingredient intended to function as an exfoliant and could be reasonably expected to increase the susceptibility to sunburn should be covered by the Guidance.

### 2. The Guidance Should Apply Only to Products Used on Areas of the Body Normally Susceptible to Sunburn

CTFA contends that FDA has not considered all product categories that can contain an AHA ingredient. When all product categories are considered, the statement that there is a possibility of sunburn from any AHA-containing product is not correct.

AHAs can be used in various products that would not reasonably be expected to increase susceptibility to sunburn, including: shampoo, hair conditioners, eyebrow pencils, antiperspirants and deodorants, nail enamels, mouthwashes, breath fresheners, and douches.

It is inconceivable that such products would cause an increase susceptibility to sunburn because of their very nature and the fact they are used on parts of the body not susceptible to sunburn. The Guidance should clearly exempt products whose use could not be expected to cause an increased susceptibility to sunburn.

### 3. Products Containing AHA Ingredients at Concentrations of One Percent (1%) or Less with a pH of 3.5 or Higher Should be Exempted

The increased susceptibility to sunburn, from the exfoliant effect of the AHAs, would be expected to show a threshold. Hence, at some concentration, even those AHAs known to be effective exfoliants would not be expected to increase the skin's susceptibility to sunburn. CTFA believes that it is essential that FDA establish a minimal threshold for concentration below which it is clear that no increased sun sensitivity will occur. At a very minimum, this should be a conservative level of one percent (1%) at a pH of 3.5. This level is well below the level of 10% where skin sensitivity to the sun was previously detected.

**4. AHA Products Should be Exempted from the Guidance When the Manufacturer or Distributor Has Competent and Reliable Scientific Evidence that a Product Containing an AHA at Any Level Does Not Increase Sun Sensitivity or the Likelihood Sunburn**

Even if such a threshold level for AHA concentration and pH is established, it also is essential that the FDA Guidance acknowledge that the specified sunburn alert is not required if a manufacturer or distributor has competent and reliable scientific evidence that a product containing an AHA at any level will not cause increased sun sensitivity or sunburn.

Such action by FDA simply recognizes the basic principle that truthful labeling based on scientific evidence must be permitted. It would be inappropriate for FDA to place regulatory pressure on a manufacturer to tell consumers that a product may increase the likelihood of sunburn or sun sensitivity when that manufacturer has evidence that demonstrates that such a statement would be untrue.

## Conclusion

These modifications to the Draft Guidance are necessary to avoid consumer confusion and the inevitable disregard of important label information that occurs when there are excessive and unnecessary directions or other information on the label. Information with respect to sunburn and sun sensitivity should be limited to those products where there is a reasonable basis for consumers to expect that increased likelihood of sunburn or sun sensitivity could occur.

CTFA strongly supports the publication of a Guidance by FDA to encourage the inclusion of a "sunburn alert" label statement on appropriate products containing AHAs.

The Guidance should be limited to suggesting a "Sunburn Alert" statement in the labeling of products:

- containing AHA ingredients intended to function as exfoliants, and
- intended to be used on areas of the body normally susceptible to sunburn.

In addition, the Guidance should specifically exempt products:

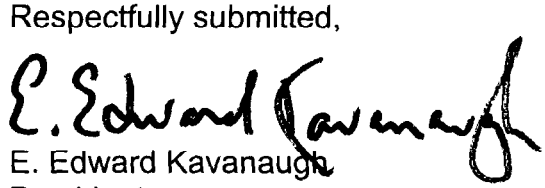
- that contain no more that a specific threshold of one percent (1%) AHA and have a pH of 3.5 or higher; or

- for which the manufacturer or distributor has competent and reliable scientific evidence demonstrating that a product containing an AHA at any level of concentration and pH does not cause increased likelihood of sunburn or sun sensitivity.

In addition, we believe the suggested label language should be modified as recommended above for products that contain sunscreen to eliminate the possibility of confusion and/or the probability that consumers will ignore a label statement that is clearly inappropriate for that particular product.

Please feel free to contact us if you have questions or need additional information.

Respectfully submitted,



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