ACCESS BUSINESS GROUP

January 31, 2003

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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Re: Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients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:

Access Business Group LLC appreciates the opportunity to comment to the draft guidance proposed for labeling products containing alpha hydroxy acids (AHA's). Access Business Group manufactures a variety of products including cosmetics and toiletries that are marketed by hundreds of thousands of independent business owners powered by the e-commerce venture Quixtar Inc. in the United States and globally via Amway distributors. Access Business Group, Quixtar, and Amway are all members of the Alticor group of companies. The products that currently containing AHA's are sold under the Artistry™ brand and other Alticor brand names.

Access Business Group, is a member of the Cosmetics, Toiletries and Fragrances Association (CTFA) and has been supportive of a Citizen Petition filed by CTFA in June 2002, requesting that FDA issue a regulation establishing sun alert labeling on AHA products. CTFA specifically requested that FDA issue a regulation establishing labeling requirements relating to sun protection for cosmetic products containing AHA's that function as exfoliants. Access Business Group supported 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.

The sun alert label language requested by CTFA is:

> "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 contrast to the FDA proposal of

> "Sun**burn** 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."

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Although we support the concept of a warning, we would like to present data in favor of providing FDA recognized exemption from the Guidance for those products for which acceptable scientific substantiation can be provided. That substantiation would consist of appropriate testing demonstrating that a product containing one or more AHA ingredients does not increase sun sensitivity beyond an "untreated skin" control. We believe that such an exemption maintains the intent of the Draft Guidance in providing appropriate consumer protection and will not confuse or mislead consumers using the product.

Further, we have read and noted a strong disagreement expressed by CTFA over the failure of the Draft Guidance to exempt products containing AHA ingredients that are not intended to function as exfoliants and thus do not present the same increased possibility of sun sensitivity or sunburn. We agree that AHA uses extend beyond exfoliating and that there is a long history of safe usage without need for sunscreen protection warnings.

We also concur with the spirit of CTFA comments regarding AHA formulations that make exfoliant claims but which also contain a sunscreen. However, we also recognize that it may be appropriate to provide additional assurance that these AHA containing products do not present sun sensitivity concern. In concert with the Cosmetic Ingredient Review panel (cited below), we believe that it is important that an equivalent to SPF 2 or greater be demonstrated in the finished product.

Access Business Group Supports a Label Statement for AHA Containing Products **that Cannot be Exempted**

The suggested label statement differs in several significant respects from the statement proposed in CTFA's Citizen Petition and supported by Access Business Group. For example, the FDA proposal identifies the presence of AHA ingredients as the reason for the statement. This unnecessarily focuses on the presence of AHA's and may erroneously lead consumers to conclude that sunscreen might not otherwise be a valuable skin protective measure. It also unnecessarily increases the complexity of the warning by urging consumers to limit sun exposure in addition to using a sunscreen and highlights the possibility of sunburn as well as increased sun sensitivity.

There are merits to a shorter, more concise warning statement for the consumer and we suggest that FDA consider an alternate warning closer to that originally proposed. Nevertheless, we believe it is important to finalize this action and encourage the inclusion of this important information on the label of appropriate AHA products. Therefore, we will not oppose the label statement as proposed for AHA products that may cause sun sensitivity problems. However, we urge FDA to reconsider whether it is necessary or prudent to recommend a label statement specifically referring to AHA's. We believe, in particular, that the presence of an AHA ingredient does not always result in increased sun sensitivity and sometimes an AHA ingredient can be used in a product highly unlikely to

cause increased sun sensitivity. Evidence is presented below in support of this view

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

1. **Products, which can demonstrate that there is no increased likelihood of sun sensitivity, should be exempted from the requirement of any warning statement.**

Access Business Group has funded a study in which AHA containing products were evaluated for a causative linkage with sun sensitivity. The evaluation was completed by an independent, well-recognized laboratory and adapted from the twelve week protocol included in the studies cited by FDA. The results of this study (appended) demonstrate that a properly formulated product can show no statistical difference in sun sensitivity from untreated skin. If no difference can be observed between the product and a "no treatment" control, we believe that the warning would only serve to confuse the public without compensatory benefit. Further, requiring the warning disadvantages those companies that expend additional effort to formulate products that provide appropriate margins of safety.

This study was presented in summary form in a poster session of the 57th Annual Meeting of the American Academy of Dermatology, March 19-24, 1999, held in New Orleans. That poster paper "The Effects of UV Light on Skin Pre-treated with Alpha Hydroxy Acid Moisturizers" by D. Aupperlee, B.S., A. Zimmerman, B.S., P. Hino, M.D., M. Sigler, Ph.D., D. Burson, B.A., T.J. Stephens, Ph.D is appended in its handout version. Comments received during and after the meeting indicated acceptance of the methodology by the scientific community.

We believe that this exemption approach is in keeping with the findings of the Cosmetic Ingredient Review recommendation. The expert panel reviewed Glycolic Acid, et al. and published that review in the CIR Compendium (see 2002 CIR Compendium, pages 98-101). In the discussion of sun sensitivity, the CIR panel cites, **"that it is easily conceivable that aspects of cosmetic product formulation could eliminate the effect. For example, inclusion of a sunscreen with an SPF of 2 would eliminate the effect. Likewise, addition of color additives or vehicles that produce even a small increase (sic) UVR reflectance would eliminate the effect."** The panel then admonishes producers of leave-on cosmetics containing AHA ingredients to **"either formulate to avoid increasing sun sensitivity (as mentioned above) or to provide directions for use that include the daily use of sun protection."** Access Business Group supports this expert panel recommendation and suggests that a definitive method of assuring formulations that do not increase sun sensitivity is to test them.

We acknowledge the suggestion by CTFA that other formula criteria can be cited which might serve as the basis for an exclusion from the required warning. Such

formula criteria would undoubtedly include the inclusion of a sunscreen at appropriate levels in the AHA containing formulation or the adjustment of pH to assure a level of free acid no greater than an agreed upon percentage in the finished formula. We recommend further study to provide assurance that these criteria result in sufficient guidance to formulators. Access Business Group is supportive of the concept of formulary guidance and could be fully supportive of the outlined position with additional data or an appropriate margin of safety as determined by the manufacturer. In any case, we suggest that FDA recognize testing with a scientifically sound protocol is an appropriate basis for exemption regardless of the concentration of AHA in the product.

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

Access Business Group joins with CTFA in urging 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, more specific advice must be given the consumer since additional sunscreen may not be required while using the AHA product. This may confuse the consumer and cause inappropriate behavior such as an unnecessary application of sunscreen or a tendency to disregard entirely a statement that appears to conflict with the formulated intent of the product. Still, we acknowledge the CIR recommendaiton that manufactures formulate to SPF 2 or greater in the finished product. For these products, the label statement should be shortened to address only the need to use a sunscreen for seven days after use of the AHA product is discontinued. Our suggested language is as follows:

> Sun Alert: This product may increase your skin's sensitivity to the sun. Use a sunscreen and for a week after use of this product is stopped.

3. Products Containing Small Amounts of an AHA Ingredient Not Intended as an Exfoliant Should be Exempted from the Guidance

Quoting, "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." It also states that while the predominant AHAs in cosmetics are glycolic and lactic acids, others found include "citric acid, -hydroxyoctanoic acid, and -hydroxydecanoic acid." 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)

Access Business Group agrees with CTFA comments that broadly defining those cosmetics that would be subject to the Draft Guidance as "all AHA containing products," is inappropriate, because:

- only products that have used AHAs for their exfoliating properties 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, and
- cosmetic product categories that do not have exfoliating use do not now cause increased susceptibility to sunburn nor would they be reasonably anticipated to do so.
- This inclusion of all AHA containing products in the Guidance does not consider that there would be an AHA concentration, specifically a free acid concentration, below which the product would not reasonably be expected to increase susceptibility to sunburn.

As noted above, the Cosmetic Ingredient Review beginning in 1994 conducted an evaluation of the safety of glycolic and lactic acids, their common salts and simple esters. During that evaluation, it was established that high concentrations of these acids (10%) could increase the skin's sensitivity to the sun (Int. J. Tox., 17(1) p. 1-241). FDA cites three complaints received between 1992 and 2000 regarding AHA products that caused sunburn, a sign of that same increased sun sensitivity. Concern regarding this linkage of AHA use for exfoliation prompted CTFA's citizen petition, cited in the Draft Guidance, in which the industry acknowledged that use of these ingredients as exfoliants could increase the skin's sensitivity to the sun. To provide appropriate safety for users, CTFA then proposed precautionary labeling for those uses.

Access Business Group concurs with CTFA's contention that FDA has not considered all product categories that can contain an AHA ingredient. When that full analysis is completed, it will become apparent that the FDA statement that there is a possibility of sunburn from any AHA-containing product is flawed. It will then become clear that only those products that have an AHA ingredient intended as an exfoliant could be reasonably expected to increase susceptibility to sunburn.

AHAs have various alternative uses in cosmetic products including: pH adjuster, chelating agent, fragrance ingredient, humectant, and skin conditioning agent – miscellaneous or occlusive (see International Cosmetic Ingredient Dictionary and Handbook). For example, citric acid (cited by FDA as an AHA ingredient) is used in formulations primarily for its ability to adjust pH. Such a use could not be reasonably anticipated to cause increased susceptibility to sunburn. Such a use should not be included in the Guidance.

In summary, the Guidance should be limited to suggesting a "Sun Alert" statement in the labeling of products:

- containing AHA ingredients <u>that function as exfoliants</u> and
- the label statement should be modified as noted above if the AHA containing product provides an appropriate level of sunscreen protection.

The FDA Guidance should clearly indicate that an exemption from any "Sun Alert" warning is appropriate

- when there is data using an appropriate scientific test methodology that demonstrates use of the product does not increase sun sensitivity above a "no treatment" control, and
- for products that are appropriately low in AHA concentration or are modified in pH to give an appropriately reduced level of free alpha hydroxy acid.

Conclusion

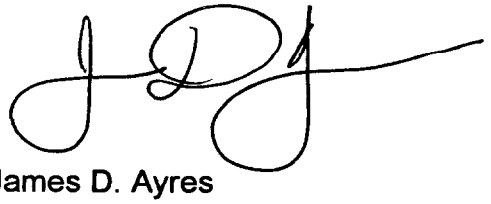
Access Business Group supports FDA publication of a Guidance to encourage the inclusion of a "sun alert" label statement on appropriate products containing AHAs.

We do not believe that a statement is necessary or appropriate when AHA containing products meet certain criteria (outlined above) or are not intended to function as exfoliants.

In addition, we believe the suggested label language should be abbreviated in all cases and modified as recommended above for products that contain sunscreen in sufficient concentration to provide adequate protection without separate application of sunscreen. This will mitigate the possibility of confusion and/or the probability that consumers will ignore a label statement that seems inappropriate for the product.

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

Respectfully submitted



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