

Procter & Gamble

Cosmetics
11050 York Road
Hunt Valley, Maryland 21030-2098

103 01 31 11:58
January 31, 2003

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

RE: Draft Guidance for Industry on Labeling
For Topically Applied Cosmetic Products
Containing Alpha-Hydroxy Acids as Ingredients
Docket No. OOP-1378

Dear Sir or Madam:

These comments are submitted on behalf of The Procter & Gamble Company in response to FDA's publication of the above captioned Guidance in 67 Fed.Reg. 71577, dated December 2, 2002. This action was taken by the Agency in response to a Citizen Petition filed by the Cosmetic, Toiletry and Fragrance Association (CTFA) on June 2002, requesting that FDA issue a regulation establishing sun alert labeling for products containing the ingredient "AHA." FDA's response was the aforementioned Guidance which expanded the original CTFA request to suggest that the labeling of a cosmetic product that contains an AHA bear the Sunburn Alert information contained in the Guidance.

Procter & Gamble endorses the comments filed by the CTFA, and wishes to reiterate their concern that insufficient data exists for the overly broad application of the Sunburn Alert for products containing AHAs, except those topically applied to the skin for the purpose of exfoliation. There are simply no published reliable data which reflect on the presence of AHAs, in shampoos, hair conditioners, nail enamels, mouthwashes, breath fresheners, fragrances, or other products that will have the consequential results suggested by the Agency, and therefore requiring a Sunburn Alert on the labeling. The Guidance should clearly exempt those products the use of which could not be expected to cause an increased susceptibility to sunburn.

Again, we further endorse the remaining CTFA comments.

Sincerely,



Carroll A. Bodie
V.P. & General Counsel

OOP-1378

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Legal Department Telefax Transmission

Cover Sheet

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