



Bristol-Myers Squibb Company

Worldwide Consumer Medicines

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January 23, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products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

Dear Sir or Madam:

Bristol-Myers Squibb Company (BMS) is responding to the "Draft Guidance for Industry on Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients; Availability" (Docket No. 00P-1378), that was published in the Federal Register on December 2, 2002. BMS currently markets Keri® Revitalizing Moisture Therapy Lotion containing both an alpha hydroxy acid (AHA) and a SPF 15 sunscreen.

BMS agrees with the proposed "Sunburn Alert" for cosmetic products containing AHA and believes this should be extended to products containing poly hydroxy acid (PHA) and or beta hydroxy acid. PHA and beta hydroxy acid, similarly to AHA, are exfoliates with the same increased skin sensitivity concern.

However for AHA, PHA or beta hydroxy acid products containing a sunscreen with a minimum SPF 15, BMS proposes the alert be modified to read as follows:

"Sunburn Alert: This product contains an alpha hydroxy acid (AHA) [insert appropriate ingredient name] that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Limit sun exposure while using this product and for a week afterwards."

While we agree that it is important to limit sun exposure, for products with a minimum of SPF 15, the statement "Use a sunscreen and" is redundant and may be confusing to consumers. Therefore we recommend that the revised warning be used for products containing AHA, PHA or beta hydroxy acid and a sunscreen which provides at least SPF 15.

Sincerely,

Allen Skupp
Director, Global Regulatory Affairs

OOP-1378

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