

Coloplast Corp.  
1940 Commerce Drive  
N. Mankato, MN 56002-8300

Telephone (507) 345-6200  
Fax (507) 345-3291



**Coloplast**

11/13/02 1-3 2105

December 16, 2002

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

Reference: Docket identifier number OOP-1378

To Whom It May Concern:

We wish to comment on the proposed advisory label recommended in the above referenced docket.

The statement recommended, "Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to sunburn. Use a sunscreen and limit sun exposure while using this products and for a week afterwards.", is quite long. Many cosmetic products are packaged in fairly small containers and it would be difficult to add this much text.

We are currently using a similar warning on our products containing AHA. Our caution statement is as follows: "**Precautions: When Using This Product:** always wear a daily sunscreen of Sun Protection Factor (SPF) 15 or higher."

An alternative and also shorter text could be: "**Caution:** Sunburn Alert: always wear a daily sunscreen of Sun Protection Factor (SPF) 15 or higher when using this product which contains alpha hydroxy acid (AHA) that may increase sun sensitivity."

We feel that both of these get the message across and should be considered acceptable.

Sincerely,

Elizabeth Boots  
Vice President, Quality Assurance

OOP-1378

C1