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February 09, 2000

Charles Ganley, MD
FDA CEDR
Division of OTC Drug Products
Attn: Document Control Room
5600 Fishers Lane, HFD - 560
Rockville, MD 20857

Dear Dr. Ganley:

This letter is in reference to Docket No. 78N-0038.

We at the American Cancer Society appreciate your interest and involvement in skin cancer prevention, and would like to solicit your assistance in removing an important obstacle faced by the general public in their attempt to safeguard their own health and the health of their families.

As you know, skin cancer is a major public health problem in the United States. It is the most common form of cancer and affects about 1.3 million people each year in this country. Fortunately, it is usually curable, but many people cannot be cured, and there is, on average, another American who dies from skin cancer every hour of the day, every day of the year. This is all the more tragic because skin cancer is so preventable by using sun protections, such as shade, clothing and sunscreens, to avoid overexposure. Sunscreens have become a mainstay of this effort, and have established themselves as a major consumer product.

There is a problem however: many sunscreens are removed from the skin by sweating or swimming. Some are not. Some degrade with prolonged exposure to the sun; others do not. It is generally impossible for the consumer to tell from the bottle how often the sunscreen needs to be reapplied to retain its effectiveness.

Because of this, health authorities have generally advised consumers to reapply the sunscreens frequently during the day. This can become both expensive and impractical for the consumer, so is usually not done.

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Although the Food and Drug Administration has set standards for labeling of the Sun Protection Factor (SPF) of sunscreens, the issue of how often consumers need to reapply the lotion to maintain protection has not yet been adequately addressed. When a sunscreen is classified as "waterproof", it will maintain protection for 80 minutes. Eighty minutes doesn't mean much for someone who wants to protect themselves all day.

The Australians have developed standards for hours of protection provided by sunscreens, so residents of Australia can tell by looking at the bottle in the store whether they will have to reapply frequently to maintain protection when outdoors. American consumers would surely appreciate and benefit from this information.

It would be very helpful if the FDA were to develop a standard which the industry could use to label their products. The marketplace would take care of the rest, propelled by consumer interest in sun protection and public information provided by health authorities and volunteer organizations, such as the American Cancer Society.

Simply put, we are asking that the consumer be informed of how long his or her sunscreen will last once applied, so that protection from overexposure can be maintained, and skin cancer prevented. Directions on the label could be: "Reapply every 4 hours", or whatever the designated test time is to maintain effectiveness under a variety of typical conditions of use. It may also be necessary to state "Reapply after towel drying" if tests show that towel drying removes the sunscreen.

Sometimes simple things are crucially important. Thank you for your help.

Sincerely,



Martin A. Weinstock, MD, Ph.D.
Chairman, American Cancer Society
Skin Cancer Advisory Group
Director, Dermatoepidemiology Unit
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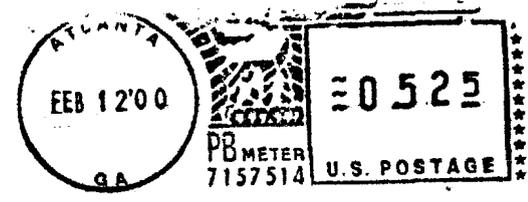
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