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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

May 24, 2000

Charles J. Ganley, M.D.
Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

E. EDWARD KAVANAUGH
PRESIDENT

Re: Final Regulation for Sunscreen Drug Products (Docket No. 78N-0038);
Proposed Labeling for High-SPF Sunscreen Products

Dear Dr. Ganley:

This submission is made in response to requests by the Food and Drug Administration (FDA) at the Sunscreen Working Group Meeting on October 26, 1999 and in a letter dated March 20, 2000 from Dr. Linda M. Katz to The Cosmetic, Toiletry, and Fragrance Association (CTFA) requesting additional information from the industry, including proposed labeling for high-SPF (SPF over 30) products. It is submitted on behalf of CTFA and the Consumer Healthcare Products Association (CHPA) which represent the interests of sunscreen manufacturers and marketers.

In its Final Monograph for OTC Sunscreen Drug Products, FDA banned labeling of Sun Protection Factor (SPF) values over 30. CTFA believes that this action, if left in place, would deprive consumers of information that is extremely important to their ability to choose appropriate sunscreen protection. The purpose of this submission is to propose labeling for high-SPF products that will address FDA concerns about how consumers might use these products, and to provide a further basis for FDA to remove the ban on labeling of the actual SPF value of these high-SPF products.

At the October 26 working group meeting, spokespersons from the American Academy of Dermatology and the Skin Cancer Foundation also expressed the strong support of the medical community for the availability and truthful labeling of high-SPF products. These medical authorities stressed that many persons with sensitive skin or who must be in the sun for prolonged periods need high-SPF products to obtain adequate protection. They also emphasized that dermatologists and other medical professionals must have this information in order to be able to accurately advise their patients of what type of sunscreen to use.

78N-0038

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036-4702

202.331.1770 FAX 202.331.1969

<http://www.ctfa.org>

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FDA has expressed a concern that consumers may infer that they can stay in the sun for longer periods of time than appropriate when they use high-SPF sunscreens. While we do not believe there is clear evidence to support that concern, the industry is willing to support mandatory labeling information that will make it clear that use of a high-SPF product is not intended to prolong time in the sun. This will help to ensure that consumers do not extend their time in the sun when using such a product. We believe that the appropriate place for such labeling is in the indications for use for such products.

As discussed at the October 26, 1999 meeting, the availability of high-SPF products is critical to protect against sub-erythral damage. We believe consumers can understand the level of sun protection associated with high-SPF sunscreen products. We strongly believe that it is inappropriate for FDA to bar manufacturers from providing accurate information on the label and in labeling about the sun protection (in terms of SPF) provided by a product with an SPF over 30.

To provide additional information about the proper use of high-SPF sunscreens, we propose the following language be a mandatory indication for all sunscreen products with an SPF above 30:

[bullet] higher SPF products give more sun protection, but are not intended to extend the time spent in the sun

Such labeling would address the concern expressed by FDA, and would provide an extra measure of protection that consumers will use these products safely and obtain the full benefit of the extra sun protection that they offer.

Enclosed please find an example of a sunscreen product label with this indication for use that would be mandatory for products with an SPF higher than 30 (Attachment A). We consider this language to be clear and concise in conveying the benefit of using high-SPF sunscreen drug products in the context of other mandatory and voluntary information provided on this sunscreen label.

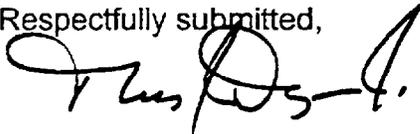
Because of advances in sunscreen formulation technology that were reviewed with the Agency staff in a June 3, 1998 feedback meeting, there are now a wide variety of products on the market. Sunscreen products not only offer a variety of different levels of sun protection, but in some cases these products are intended to serve a particular need. For example, some products are designed for use during extended periods of direct sun exposure (such as time at the beach or during participation in sports) while others are intended for daily sun protection while at work or running daily errands. Some products are intended for several uses.

An appropriate range of "indications for use" is essential to ensure that the consumer is not confused and understands the appropriate uses for the actual product in hand. We intend to submit additional indications for sunscreen products and directions to the Agency in the near future.

We have now provided all of the information requested by FDA related to the high-SPF issue, and believe we have provided justification for removing the bar to SPF claims over 30. Because of the importance of this issue, we request immediate feedback from the Agency. In particular, it is critical that we be advised of any additional questions or information required by the Agency in sufficient time to respond before the end of the opportunity to comment on necessary amendments to the final monograph. If clarification or additional information would be useful, we would be pleased to meet with you at your convenience.

Please contact us if you have any questions or concerns. We are working to respond to the remaining outstanding issues related to sunscreen drug products and will do so as soon as possible.

Respectfully submitted,



Thomas J. Donegan, Jr.
Vice President-Legal & General Counsel

cc: Robert J. DeLap, M.D. (HFD-105)
Linda M. Katz, M.D. (HFD-560)
John D. Lipnicki (HFD-560)
Donald Dobbs (HFD-560)
Dockets Management Branch (HFA-105)

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Coppertone

SPF 45

Sunscreen Lotion
UVA/UVB PROTECTION

Very Water Resistant
Ultra-Moisturizing with
Aloe & Vitamin E

12 FL OZ (354 mL)

06846-03

Make the most of your time in the sun with America's leading sunscreen brand, Coppertone® sunscreen!

SUN ALERT: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

Drug Facts

| Active ingredients | Purpose |
|---------------------------------|------------|
| Homosalate 8% V/V | Sunscreens |
| Octyl methoxycinnamate 7.5% V/V | |
| Octyl salicylate 5% V/V | |
| Oxybenzone 6% V/V | |

Uses • helps prevent sunburn • higher SPF products give more sun protection, but are not intended to extend the time spent in the sun • retains SPF after 80 minutes of activity in the water • provides high protection against sunburn • for skin highly sensitive to sunburn

Warnings
• For external use only
• When using this product keep out of eyes. Rinse with water to remove.
• Stop use and seek a doctor if rash or irritation develops and lasts.
• Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • apply liberally and evenly before sun exposure • children under 6 months of age: ask a doctor • reapply as needed, or after towel drying, swimming, perspiring, or vigorous activity

Inactive ingredients Water, Sorbitan isostearate, Sorbitol, Polyglyceryl-3 Distearate, Octadecene/MA Copolymer, Triethanolamine, Stearic Acid, Barium Sulfate, Benzyl Alcohol, Dimethicone, Methylparaben, Aloe Barbadosis Extract, Jojoba Oil, Tocopherol (Vitamin E), Imidazolidinyl Urea, Propylparaben, Carbomer, Fragrance, Disodium EDTA.

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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION
101 17TH STREET, N.W., SUITE 300
WASHINGTON, D.C. 20036-4702

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The Cosmetic, Toiletry, and Fragrance Association

*1101 17th Street, N.W., Suite 300
Washington, D.C. 20036 • 202/331-1770*

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