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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

E. EDWARD KAVANAUGH
P R E S I D E N T

October 9, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Docket No. 2003N-0233: Notice of eligibility; request for data and information

Dear Sir or Madam:

On July 11, 2003, the Food and Drug Administration (FDA) published a notice of eligibility and request for data and information on three sunscreen active ingredients: amiloxate (isoamyl p-methoxycinnamate), up to 10 percent as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; enzacamene (methyl benzylidene camphor), up to 4 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients; and octyl triazone, up to 5 percent, as a sunscreen single active ingredient and in combination with other sunscreen active ingredients.

This letter is submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA) and Consumer Healthcare Products Association (CHPA). Founded in 1884, CTFA has an active membership of more than 300 companies that manufacture or distribute most of the finished personal care products marketed in the United States. CTFA members market or manufacture the vast majority of sunscreen products sold in the U.S., as well as a large number of other OTC drugs and cosmetic-drugs. CTFA members also export sunscreen products throughout the world, and many members have manufacturing plants located outside the U.S. We also represent approximately 300 associate members who provide goods and service to manufacturers and distributors of personal care products. Founded in 1881, CHPA is the national association representing manufacturers and distributors of OTC drugs and nutritional supplements. CHPA member products include sunscreen drug products.


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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CTFA and CHPA support regulatory action that allows industry to develop and market additional safe and efficacious sunscreen products. Approval of more sunscreen active ingredients expands the formulation options that allow the industry to produce a wide variety of sunscreen products intended to protect the public against the hazards associated with sun exposure.

Because of the significant public health benefits that sunscreen products provide, CTFA and CHPA support the Agency's timely review of the data and information to be provided.

Sincerely,



Thomas J. Donegan, Jr.
Vice President – Legal & General Counsel
The Cosmetic, Toiletry, and Fragrance Association



Eve E. Bachrach
Senior Vice President, General Counsel and Secretary
Consumer Healthcare Products Association

cc: Charles J. Ganley, M.D. (HFD-560)
Matthew R. Holman (HFD-560)