



E. Edward Kavanaugh
President

December 2, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Over-the-Counter Human Drugs; Labeling Requirements; Delay of
Implementation Date, Docket Nos. 1998N-0337, 1996N-0420,
1995N-0259, and 1990P-0201

These comments are submitted on behalf of The Cosmetic, Toiletry, and
Fragrance Association (CTFA) in response to FDA's "Over-the-Counter Human
Drugs; Labeling Requirements; Delay of Implementation Date," published in
69 Fed. Reg. 53801 (September 3, 2004).

In the *Federal Register* of September 3, 2004, the Food and Drug Administration
(FDA) published a delay of the implementation date for sunscreen drug products
subject to the final rule that established standardized format and content
requirements for the labeling of over-the-counter (OTC) drug products (drug facts
rule). The drug facts rule requires that all OTC drug products be labeled
according to established requirements codified in 21 CFR 201.66. Compliance
dates for the drug facts rule vary according to the regulatory status of the
products.

CTFA is the national trade association representing the personal care products
industry. CTFA's membership includes the manufacturers and distributors of a
large percentage of sunscreen products that are regulated as drugs in the United
States. These sun care products are sold in a wide variety of formulations, many
of which are intended to provide a cosmetic benefit (e.g., imparting color to the
skin, skin moisturization) as well as a drug benefit (sun protection). These
products are regulated both as drugs and cosmetics. Because they are
regulated as drugs, they are subject to the requirements of the drug facts rule,
the sunscreen monograph, and other drug regulations as well as FDA's
regulations for cosmetics.

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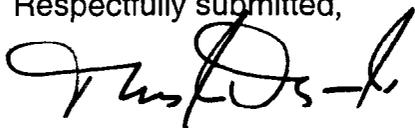
For these reasons, CTFA has had a longstanding and active interest in the development of the drug facts rule and its impact on sunscreens and other personal care products that provide both cosmetic and drug benefits. As we have indicated in comments previously filed on the public records of the drug facts rule and other monographs, there are still a number of labeling issues that require further consideration. There are products that cannot comply with the requirements of the drug facts rule. Most at risk are those products in smaller packages that provide convenience and ease of use for an increasingly mobile population.

CTFA and its members support the Agency's postponement of the implementation date of the drug facts rule as it applies to OTC sunscreen drug products. FDA has stayed the final monograph for OTC sunscreen drug products pending publication of future amendments to the sunscreen final monograph that will address outstanding issues of testing and labeling. CTFA has filed numerous comments on a variety of labeling issues related to sunscreen products, including comments on UVA and SPF labeling, anti-aging claims, and the need for greater flexibility in indications and directions for use for sunscreens, as well as specific requests that FDA revise the final sunscreen monograph to permit modifications to certain requirements of the drug facts rule (August 4, 2000 and January 5, 2001.)

Lastly, the process of reformatting and redesigning labels to implement the requirements of the drug facts rule as it applies to OTC sunscreen drug products will be a lengthy undertaking. Industry will need sufficient time to comply with the requirements of the amended final monograph in terms of labeling and/or packaging changes, as well as potential issues of retesting and reformulation. We have filed comments urging the Agency to consider this factor of time and look forward to learning proposed implementation dates when the FDA's proposed amendment to the final sunscreen rule is published.

We appreciate the opportunity to provide these comments. Please feel free to contact us if you have questions or need additional information.

Respectfully submitted,



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