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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

July 7, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20857

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

Re: Petition for Reconsideration and Petition for Stay of Action;  
Final Monograph on Skin Protectant Drug Products for  
Over-the-Counter Human Use:  
Docket Nos. 78N-0021 and 78N-021P

This Petition is submitted by The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA")<sup>1</sup> in accordance with 21 CFR 10.33(b) and 10.35(b). We are asking for reconsideration and a stay of action of certain decisions by the Agency in the Final Monograph for Skin Protectant Drug Products for Over-the-Counter Human Use, 68 FR 33362 (June 9, 2003).

*A. Decision involved*

CTFA submits this petition to request the Agency to reconsider its decisions to eliminate the terms "helps prevent" and "chafing" from the indications in 21 CFR 347 for Over-the-Counter Monograph Skin Protectant drug products. CTFA also submits this petition to stay the effect of this rulemaking on such claims until the matter has been resolved.

*B. Action requested*

CTFA requests the Commissioner to amend the Final Skin Protectant Monograph to permit "helps prevent" and "chafed" in the indications in 21 CFR 347 for Over-the-Counter Monograph Skin Protectant drug products.

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<sup>1</sup>CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. Founded in 1894, CTFA has approximately 600 members involved in manufacturing and distributing personal care products throughout the United States.

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Furthermore CTFA requests the Commissioner to stay any enforcement action regarding such claims until the Agency has acted on this petition.

### *C. Statement of grounds*

In the Tentative Final Monograph published February 15, 1983 (48 FR 6820) the FDA proposed the following indication for skin protectant products, "helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips." This indication was proposed for skin protectant drug products containing specific approved ingredients in sec. 347.10, namely allantoin, cocoa butter, dimethicone, glycerin, petrolatum, shark liver oil and white petrolatum. Sec. 347.50 (b)(2).

In the Final Monograph for skin protectant products published June 4, 2003, the indication in 21 CFR 347.50(b)(2) was modified: "helps prevent" and "chafed" were deleted, so that the indications now state, (i) "'temporarily protects' (which may be followed by: 'and helps relieve') 'chapped or cracked skin' (which may be followed by: 'and lips')," and (ii) "'temporarily protects' (which may be followed by: 'and helps relieve') 'chapped or cracked lips'."

In the preamble to the Final Monograph the Agency explained its decision that glycerin at concentrations other than 20 to 45 percent is nonmonograph for use in OTC skin protectant drug products, stating that the submitted data failed to demonstrate the indication "helps prevent and temporarily protects chafed, chapped, cracked, or windburned skin and lips." However, the phrases "helps prevent" and "chafed" have been deleted from the indication for all Monograph skin protectant ingredients, not just those that contain glycerin.

The Agency has not adequately explained its reasons for deleting the phrase "helps prevent" from the indications for other Monograph Skin Protectant ingredients such as petrolatum and white petrolatum. While it has provided explanation for its decision regarding skin protectant products that contain glycerin, it has not provided adequate justification or discussion for the elimination of this claim for other skin protectant drug products.

Skin protectant products are selected frequently for their preventative as well as protective benefits. "Helps prevent" in the context of dry lips, e.g., carries a different meaning to the consumer than "temporarily protects" and "helps relieve."

There are sound legal and public policy grounds for the Agency to reconsider its decision to remove "helps prevent" and "chafed" from the indications from the Final Monograph. First, the Agency has failed to explain or

justify its elimination of all use of the terms "helps prevent" or "chafed." In the twenty years that have elapsed, consumers and manufacturers have acted in reliance of this indication proposed by the Agency to be an effective indication for self-selection of these drug products. Those label statements were made in furtherance of FDA's own policy stated in the Tentative Final Monograph, that "...the agency believes that stating that the product helps prevent or temporarily protects chafed and chapped skin or lips is more informative to the consumer." 48 FR 6820, at 6828.

Furthermore the Agency recognized the preventative use of skin protectants in the discussion of the Tentative Final Monograph by stating "the word 'exposed' also describes the drug use of the product when it is used for prevention purposes, such as *to prevent* chafing or windburn." 48 FR 6820 at 6823 (emphasis added). "Chafed" has been removed from 21 CFR 347.50(b)(2)(ii) as well.

Consumers have in the course of the twenty years of the Tentative Final Monograph, come to understand the difference between "chafing" and "chapping". The American Heritage Dictionary, Second Edition, defines "chafe" as "to wear away or irritate by rubbing; to become worn or sore from rubbing". "Chap" is defined as "to cause to split or roughen, especially as a result of cold or exposure".

Medical experts have drawn a distinction between chafing and chapping, yet use and recommend skin protectants to treat both skin conditions. Stedman's Medical Dictionary defines "chafe" as "to cause irritation of the skin by friction"; while "chapped" is defined as "having or relating to skin that is dry, scaly, and fissured, owing to excessive evaporation of moisture from the skin surface".

Manufacturers have labeled skin protectant products with "helps prevent" in accordance with the proposed indications of the Tentative Final Monograph published more than twenty years ago. FDA has not provided substantiation for its elimination of "helps prevent" and "chafed" from the indications for all skin protectant products. Whether this was deliberate or an oversight, we believe the record and the long history of use of these claims justifies reconsideration and reinstatement of these important indications.

Furthermore CTFA believes the Agency has failed to meet the requirements of the Administrative Procedure Act and its regulations for implementing the Act. The preamble to a final regulation must "contain a thorough and comprehensive explanation of the reasons for the Commissioner's decision on each issue." 21 CFR 40(c)(3). The Agency is silent, providing no explanation for its decision to eliminate two separate and

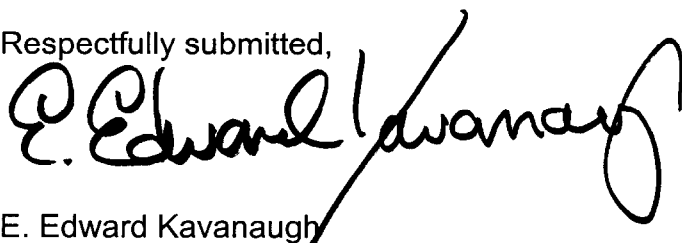
important label indications that it previously proposed. In addition, the Agency has not provided adequate notice and opportunity for public comment on the action taken. The Agency's actions can only be viewed as arbitrary and without adequate explanation.

*D. Conclusion*

CTFA requests the Commissioner to reconsider and revoke the Agency's decision in 21 CFR 347.50(b)(2) to eliminate the terms "helps prevent" and "chafing" for skin protectant drug products. While this decision is pending, the Commissioner is requested to stay the effective date of June 4, 2004 for relevant portions of this Final Monograph.

CTFA would be pleased to provide further information or clarification as needed.

Respectfully submitted,

A handwritten signature in black ink that reads "E. Edward Kavanaugh". The signature is written in a cursive style with a large, sweeping flourish at the end.

E. Edward Kavanaugh  
President  
The Cosmetic, Toiletry, and Fragrance Association

cc: Charles J. Ganley, M.D. (HFD-560)  
Gerald M. Rachanow (HFD-560)  
Daniel E. Troy, Esq. (GCF-1)