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TOILETRY, AND  
FRAGRANCE  
ASSOCIATION

SDA

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May 23, 2003

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
12420 Parklawn Drive  
Rockville, Maryland 20857

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**CITIZEN PETITION: DOCKET 75N-183H**

Dear Sir or Madam:

This Citizen Petition is submitted under 21 CFR 10.30 on behalf of The Soap and Detergent Association and The Cosmetic, Toiletry, and Fragrance Association (the "Industry Coalition" or "Petitioner"). This Citizen Petition requests the Commissioner of Food and Drugs to take the following action with respect to the OTC Topical Antimicrobial Drug Products Review, including the Tentative Final Monograph for OTC Health Care Antiseptic Drug Products, 21 CFR Part 333, Subpart E (the "TFM").

**ACTION REQUESTED**

The Petitioner requests the Commissioner to reopen the administrative record of the TFM solely for the purpose of including the attached information in developing the final OTC drug monograph for healthcare antiseptic drug products and in future deliberations regarding a Final Monograph for other categories of topical antimicrobial products.

**STATEMENT OF GROUNDS**

The time specified for comment on the TFM, published June 17, 1994, has lapsed. See 21 CFR Sec. 330.10 (a)(7)(iii). The Agency's regulations recognize, however, that the administrative record of a tentative final monograph may be reopened to consider new data and information, see 21 CFR Sec. 330.10(a)(10)(iii), and that new data and information may be considered by the Commissioner prior to issuing a final monograph for good cause shown. 21 CFR Sec. 330.10 (a)(7)(v).

In August 2001, recognizing that the Agency was developing a Monograph for products designated as "healthcare professional products" the Industry Coalition submitted a Citizen Petition that included performance criteria for pre-operative skin preparations, surgical scrubs and healthcare personnel hand products. This Citizen Petition complements the August 2001 healthcare professional products submission by providing data to support performance criteria

CTFA is the national trade association representing the cosmetic, toiletry and fragrance industry. Founded in 1894, CTFA has an active membership of approximately 300 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also includes approximately 300 associate member companies, including manufacturers of raw materials, trade and consumer magazines, and other related industries.

The Soap and Detergent Association is the non-profit trade association representing some 120 North American manufacturers of household, industrial and institutional cleaning products, their ingredients, and finished packaging. SDA members produce more than 90% of the cleaning products marketed in the U.S.

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for the remaining product categories that comprise the HCCM, namely food handler, consumer hand and consumer body products.

This Citizen Petition provides a comprehensive literature review for topical antimicrobial consumer products, including food handler, consumer hand and consumer body products. Importantly, the literature establishes the prophylactic benefits that can be obtained from the use of topical antimicrobial hand and body products. These benefits are corroborated by a number of studies in which quantitative microbial risk assessment, or Risk Modeling, has been performed. Additionally, based on consideration of the existing literature, the Petition provides proposed performance criteria for the consumer product categories.

It is important to note that inclusion of the attached materials in the body of evidence considered by FDA in the development of the Final Monograph for OTC Health Care Antiseptic Products is essential if FDA is to base its decisions on the most current scientific information. More than seven years have passed since the record of the TFM closed, and, at public meetings since that event (e.g., a November 3, 1999 FDA feedback meeting) FDA has indicated the need for further information regarding these products. The attached material is intended to satisfy that need and is relevant to the Agency's decisions with respect to the conditions under which topical antimicrobial products may be marketed.

It is also important to note that this Petition is not typical of other Citizen Petitions received by the Agency. We are not asking the FDA to adopt any significant new policies by this Petition. Instead, we are asking the Agency to consider this material that is directly relevant to actions previously discussed with and requested of FDA.

The information provided in this Petition, together with the petitions that have been submitted over the past years, provides data in support of one consolidated Monograph. Should the Agency decide that rulemaking for food handler products, consumer hand products, and consumer body products will be considered separately at a later date, we request that a statement be added in the Final Monograph for healthcare professional products that confirms that decision.

In sum, the attached material is directly relevant to the proposed conditions under which antimicrobial products may be marketed. Good cause exists for the Commissioner to consider this material because it includes and integrates medical and scientific data that was not available until after the close of the record more than seven years ago, and it is responsive to questions raised by FDA during public meetings since that time.

#### **ENVIRONMENTAL IMPACT**

According to 21 CFR 25.31(c), this Petition qualifies for a categorical exclusion from the requirement that an environmental assessment be submitted.

**ECONOMIC IMPACT**

According to 21 CFR Sec. 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of this Petition.

**CERTIFICATION**

The undersigned certify that, to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data known to the Petitioner which are unfavorable to the Petition.

Respectfully submitted,



Richard I. Sedlak  
Vice President of Technical and  
International Affairs  
Soap and Detergent Association



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

cc: Charles J. Ganley, M.D. (HFD-560)  
Ms. Debbie L. Lumpkins (HFD-560)

**The Consumer Products Citizen Petition**

**May 23, 2003**

**Submitted by**

**The Soap and Detergent Association  
and  
The Cosmetic, Toiletry, and Fragrance  
Association  
Industry Coalition**

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