



The Soap and Detergent Association
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October 6, 2005

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

**Re: Healthcare Continuum Model; follow up to NDAC meeting
 March 23, 2005; Dockets No. 75N-183H**

Dear Sir or Madam:

On March 23, 2005 the FDA convened a meeting of the Non-prescription Drugs Advisory Committee (NDAC) to discuss issues associated with the effectiveness of topical antiseptic products used in health care settings pursuant to the June 17, 1994 Tentative Final Monograph for Health-Care Antiseptic Drug Products [59 FR 31401] (the TFM). The purpose of this letter is to formally document the position of the SDA/CTFA Industry Coalition on the need to demonstrate cumulative activity for all topical antimicrobial products in the Health Care Continuum Model, including those used in health care settings. As discussed below, we do not believe that there should be a Monograph requirement to demonstrate cumulative activity. We request that this recommendation is taken into account in further meetings and any subsequent rule-making associated with topical antibacterial products in the Health Care Continuum Model.

Requirement for cumulative activity

The need for demonstration of cumulative activity was discussed by the Panel during the March 2005 NDAC meeting. FDA personnel indicated that the historic reason for this measure "is lost to time", but may be associated with getting "more than one piece of information from these studies, one of them being effectiveness over time and the other

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091

one being the potential for irritation” (pages 178 & 179 transcript of NDAC meeting March 23, 2005).

During the meeting Panel members discussed the value of the cumulative efficacy requirement, and there were differing opinions. However, Dr. John Boyce, Clinical Professor, Department of Internal Medicine, Yale School of Medicine indicated that “the risk of the patients developing an infection isn’t related to whether you take care of them after your first wash or after your 10th wash. So, frankly, I just fail to not only see any evidence, I fail to see the logic in requiring a cumulative activity in something that is used 20, 30 or 40 times a day during the work shift” (page 198 transcript of NDAC meeting March 23, 2005). Similarly, Dr. Elaine Larson, Associate Dean, Professor of

Pharmaceutical and Therapeutic Nursing, Columbia University, School of Nursing and Professor, Department of Epidemiology, Mailman School of Public Health, Columbia University indicated that the hands should be “as clean as they can be every time you touch a patient from the beginning wash and there is no reason, that I can see, why it should be better after 10 washes” (page 352 transcript of NDAC meeting March 23, 2005).

The Industry Coalition agrees with Dr. Boyce and Dr. Larson’s comments. The most relevant time for determining efficacy of antibacterial products is immediately after product use, that is after a single wash. Topical antibacterial products should work immediately after they have been used. Evaluation of cumulative activity after ten-washes is a redundant measure that does not reflect the importance of immediate effectiveness, and should not be included in the Final Monograph as an efficacy test parameter.

With respect to product safety, measurement of cumulative activity is not the most appropriate manner by which to assess the potential of finished products to cause irritation. Standardized dermatological tests are available to evaluate the potential for skin irritation (see S.M. Pati, E. Patrick and H.I. Maibach, *Animal, Human, and in-vitro Test Methods for Predicting Skin Irritation* in *Dermatoxicity*, chap. 33, 5th ed. and the SDA/CTFA Industry Coalition Citizen Petition, August 6, 2001, Section 6 ‘*The irritation potential of topical antimicrobial wash products*’), and the Industry routinely uses protocols such as these to predict irritation potential prior to introducing cosmetic and OTC drug products to the market. The Industry Coalition recommends that FDA follow the precedent set by other topical OTC Monographs, where there is currently no mandatory Monograph requirement to demonstrate the irritation potential of finished products.

Based on the fact that topical antibacterial products should be effective the first time that they are used, and that irritation potential is best demonstrated using standardized dermatological methods, the Industry Coalition believes that the TFM requirement to show cumulative activity is a redundant measure. We respectfully request that any

future discussions on the proposed Monograph reflect the Industry Coalition's recommendation that there is:

- No requirement for demonstrating cumulative activity for any of the topical antibacterial product categories in the Health Care Continuum Model.

Respectfully submitted,



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