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March 25, 2014

Ms. Leslie Kux
Assistant Commissioner for Policy
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-1975-N-0012, Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) for the opportunity to provide input into the proposed rule. APIC is a non-profit, multi-disciplinary organization representing over 15,000 infection preventionists, whose mission is to create a safer world through prevention of infection. Our comments primarily reflect the views of our members, whose responsibilities include promotion of hand hygiene as a standard practice to prevent the spread of infection.

APIC is encouraged that the FDA is undertaking evaluation of consumer antiseptic personal care products, which demonstrates an ongoing commitment to improving the safety and efficacy of these products. We are writing in support of the need for ongoing studies to evaluate the safety and efficacy of antiseptics in consumer personal care products, yet have some concerns regarding current marketing practices.

The proposed rule highlights the need for clinical outcome studies that assess the safety and effectiveness of over-the-counter (OTC) antiseptic personal care products. Specifically, the rule states that the record does not currently contain sufficient data to show that there is any additional benefit from the use of consumer antiseptic hand or body washes compared to non-antibacterial soap and water. In addition, the proposal acknowledges the potential risks from systemic absorption and long-term exposure to antiseptic active ingredients and the potential for widespread antiseptic use to promote the development of antibiotic-resistant bacteria. Lastly, the report notes the persistence of low levels of some consumer antiseptic wash active ingredients in the environment. As such, APIC supports objective research by skilled investigators who have access to consumers to demonstrate true safety and efficacy of OTC antiseptic personal care products.

In the meantime, we support the FDA's ongoing reviews of currently marketed products for risks to human health and the environment while weighing the comments and concerns from industry. We stress the need to conduct independent studies for validating the safety and effectiveness of antiseptics used in personal care products. Given the historical bias in industry-sponsored outcome studies[1], the studies must be completed by impartial scientists.

APIC is concerned about current industry-sponsored marketing efforts that suggest the unproven effect of consumer antiseptic products on preventing infections[2]. We base this concern on a recent systematic review of the efficacy of antimicrobial (i.e., triclosan) soaps compared to plain soaps. The study found that antimicrobial soaps were no more effective at preventing infectious illness symptoms or reducing bacterial levels on hands than plain soap[3]. In conclusion, APIC does not advocate the use of antiseptic products which are marketed with the implication of preventing infections without clear data to demonstrate clinical benefit.

Thank you for the opportunity to review this proposed rule and provide input on behalf of our members.

Sincerely,

Jennie L. Mayfield, BSN, MPH, CIC
2014 APIC President

[1] Lundh A, et al. Cochrane Database Syst Rev. 2012; 12.
[2] Association for Professionals in Infection Control and Epidemiology (APIC) 1997 Guidelines Committee. The use of antimicrobial household products. APIC News 1997;November/December:13.
[3] Aiello AE, Larson EL, Levy SB. Clin Infect Dis 2007;45:S137-47.