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

Re: Proposed Rule; Reopening of the Administrative Record for Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Health-Care Antiseptic Drug Products. 68 Fed. Reg. 32003 (May 29, 2003). [Docket No. 75N-183H]

Dear Sir or Madam:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates this opportunity to comment on FDA's reopening of the administrative record regarding the tentative final monograph for Over-the-Counter (OTC) Health-Care Antiseptic Drug Products, 59 Fed. Reg., 31402 (June 17, 1994) (1994 TFM). Our comments will address issues concerning only products within the Antiseptic Handwash/Health-Care Personnel Handwash category (§333.410(a)).

APIC is concerned that the 1994 tentative final monograph (TFM), as currently written, does not give credence to recent scientific evidence on the clinical effectiveness of alcohol-based hand disinfectants. This would ostensibly result in the unavailability of these products as currently marketed – the use of which has become standard practice in health care facilities across the continuum of care and has subsequently had a significant impact on health care, by reducing health care-associated infections and the transmission of resistant organisms as documented in recent scientific literature.

Furthermore, this would become a significant public health issue, as it would undermine our long-standing efforts to improve and increase hand hygiene compliance. In order to adequately address these issues, we urge that a final monograph recognize the proven efficacy and appropriateness of these alcohol-based hand products. This could be accomplished by eliminating the persistence/cumulative requirement for alcohol hand antiseptics.

In her formal comments to the FDA on this matter, Dr. Elaine Larson, eminent researcher and world renowned expert on the subject of hand hygiene, as well as Editor of our peer-reviewed journal, *AJIC (American Journal of Infection Control)*, stated that “test performance criteria should be limited to the first wash, thereby correlating with actual conditions of use and the established history of current product effectiveness.”

We defer to Dr. Larson's clinical and research expertise regarding the details of test methodologies and performance criteria in this area, as well as her concerns about the subsequent reformulation of these products in order to meet the persistence/cumulative effect requirement, if the final monograph is not

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amended. We would add to that our concern about the potential increase in the incidence of hand dermatitis if these products are altered, as well as the potential for significant delay in the approval of products needing to meet FDA testing requirements. Even more compelling, Dr. Larson cites significant potential health risks associated with the introduction of a secondary biocide into the formula in order to meet the persistence/cumulative effect requirement.

“Non-rinse (waterless) products pose higher dermal exposure levels to the residual biocides than traditional handwashing compounds, have unknown long term effects upon natural skin flora, pose at least a theoretical risk of increased odds of developing biocide-resistant organisms, and may convey a false sense of security to users, based on the belief that a ‘long lasting’ formula provides a type of ongoing barrier protection... Alcohol-based hand antiseptics in this category are intended for frequent, rapid skin degerming and a cumulative/persistent effect is not a necessary attribute.”

In 2002, the Centers for Disease Control and Prevention’s (CDC) Healthcare Infection Control Practices Advisory Committee (HICPAC), which is appointed by the U.S. Secretary of Health and Human Services, acknowledged the growing scientific literature demonstrating the significant impact of alcohol hand hygiene products on improving decontamination of hands and increasing compliance, resulting in the reduction of health care-associated infections. The Committee, which advises the Secretary on national health priorities, initiated a multidisciplinary task force to develop a comprehensive science-based guideline that included the latest advances in the area of hand hygiene. All members and liaisons to this committee, including the FDA liaison, participated in the guideline review and development process. FDA also provided pre-release clearance for this document.

The final product was issued in October 2002, by the CDC, as the new science-based publication, “Guideline for Hand Hygiene in Health-Care Settings.” These recommendations have been endorsed by many professional organizations and implemented by healthcare facilities across the country. These guidelines specifically address and recommend the use of alcohol-based hand hygiene products, concluding, “Alcohol-based hand rubs are the most efficacious agents for reducing the number of bacteria on the hands of personnel...” The guideline also recommends these products “for routine decontamination of hands for all clinical indications (except when hands are visibly soiled) and as one of the options for surgical hand hygiene.”

Implementation of these evidence-based recommendations has resulted in 1) a decrease in skin irritation in health care workers; 2) a decrease in the amount of time required to decontaminate hands, thus freeing busy health care professionals to provide care; 3) a decrease in health care-associated infections, and 4) a decrease in the transmission of resistant organisms within a care unit. Clearly, this document has had a critical impact on improving health care.

We also ask that you consider that the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) has directly included the use of alcohol-based hand de-germers with two recent issuances, both of which directly advocate the use of alcohol-based hand disinfectants by quoting the CDC Guideline for Hand Hygiene. First, the 2003 Sentinel Event Alert #28 which states, “JCAHO recommends that health organizations: 1) Comply with the CDC’s new hand hygiene guidelines; and 2) Manage as sentinel events all identified cases of death and major...” Second, the 2004 National Patient Safety Goal #7, which states, “Reduce the risk of healthcare-acquired infections. a) Comply with current CDC hand hygiene guidelines; and b) Manage as sentinel events...”

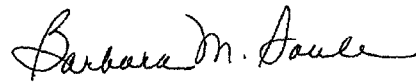
FDA’s failure to acknowledge the existence, efficacy and appropriateness of these products will raise questions and inconsistent practices in the health care community, as facilities attempt to comply with CDC and JCAHO requirements, which are based in the science of preventing nosocomial disease transmission. Furthermore, in light of the Institute of Medicine’s (IOM) patient safety directives, it has become clear in recent years that we must remove barriers that prevent implementation of reasonable

infection control measures. Any oversight in this regard could have serious patient care implications and negate the benefits that have been clearly associated in the medical literature with the full implementation of a comprehensive hand hygiene program.

We are grateful for this opportunity to offer comment and invite you to contact us if we may be of further assistance to you in this effort. Please do not hesitate to contact Jennifer Thomas Barrows, APIC's Director of Public Policy, at 860-675-6869 or jthomas@apic.org should you require any follow up information or clarification. We thank you for your kind consideration to our concerns.

APIC is a nonprofit, voluntary, international organization that promotes wellness and prevents illness and infection worldwide by advancing health care epidemiology through education, research, collaboration, practice and credentialing. APIC's vision is to improve the health of people worldwide by serving as the pre-eminent voice for excellence in the prevention and control of infections and related disease outcomes.

Sincerely,

A handwritten signature in cursive script that reads "Barbara M. Soule".

Barbara M. Soule, RN, CIC
2003 APIC President

REFERENCES

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Joint Commission on the Accreditation of Healthcare Organizations (JCAHO); 2004 National Patient Safety Goals (JCAHO documents may be found at www.jcaho.org)

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Web Sites

Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) – www.jcaho.org

Association for Professionals in Infection Control and Epidemiology (APIC) – www.apic.org

Society of Healthcare Epidemiologists of America (SHEA) – www.shea-online.org

HICPAC – www.cdc.gov/ncidod/hip/HICPAC

Infectious Disease Society of America (IDSA) – www.idsociety.org