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Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333
August 26, 2003

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

Dear Sir/Madam;

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]

In October 2002, the Centers for Disease Control and Prevention (CDC) and the Healthcare Infection Control Practices Advisory Committee (HICPAC) issued an evidence-based guideline for hand hygiene in healthcare settings. This guideline was based on scientific evidence that had accrued since the issuance of the Food and Drug Administration's Tentative Final Monograph in 1994. The new hand hygiene guideline recommends the use of alcohol-based hand rubs for healthcare worker hand hygiene based on several documented advantages of alcohol-based hand rubs over traditional soap and water handwashing when the healthcare workers' hands are not visibly soiled. Specifically, when compared with soap and water handwashing, alcohol-based hand rubs more effectively remove bacteria from hands, cause less skin irritation/dermatitis, can be made more accessible than sinks, and require less time to use, thus saving personnel time. Importantly, these latter factors have been shown to be important barriers to handwashing adherence in healthcare settings.

The link between hand hygiene and healthcare-associated infection is well established. Because alcohol-based hand rubs overcome many of the barriers to handwashing adherence by HCWs, their use will be an important strategy for prevention of healthcare-associated infections. The criteria in the proposed rule, if adopted, could substantially impede implementation of these evidence-based patient safety recommendations. Enclosed for your review is a copy of the full CDC/HICPAC Guideline for Hand Hygiene in Healthcare Setting. We submit the guideline and supporting references as part of our comments.

Thanks for the opportunity to provide comments on this important patient safety issue.

75N-183H

C73

Sincerely,

A handwritten signature in black ink, appearing to read "Michele L. Fen", with a long horizontal flourish extending to the right.

Deputy Chief, Prevention and Evaluation Branch
Executive Secretary, HICPAC
Division of Healthcare Quality Promotion
National Center for infectious Diseases
Centers for Disease Control and Prevention

Enclosure

cc: Steve Solomon, MD
Jane Siegel, MD
Robert Weinstein, MD
Denise Cardo, MD