



AMERICAN  
SOCIETY FOR  
MICROBIOLOGY

Public and Scientific Affairs Board

January 5, 2007

Division of Dockets Management  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

RE: Citizen Petition Docket # 2006P-0271 (dated 21 June 2006)

The American Society for Microbiology (ASM), the largest, single life sciences Society representing approximately 43,000 members is writing to encourage the Food and Drug Administration (FDA) to take the action requested by the Clinical and Laboratory Standards Institute (CLSI) in the above referenced Citizen Petition.

Antimicrobial resistance is a public health problem of vast importance in the United States. Clinical microbiology laboratories in this country serve as sentinels for detection of resistance. As such, this critically imperative role is facilitated by laboratory adherence to the universally accepted standards for antimicrobial susceptibility testing promulgated by CLSI through its consensus-driven standards development process. Frequent revisions and additions to these standards are made necessary by emerging antimicrobial resistance mechanisms. Accordingly, a new document incorporating these changes is issued by CLSI on an annual basis.

Due to the evolution of new resistance mechanisms, there are occasions in which CLSI interpretive criteria must be modified from those established by the FDA in order for laboratories to accurately recognize clinically important resistance. We strongly support the recommendation in the CLSI Citizen Petition to allow clinical microbiology laboratory directors and their medical staff to apply either the FDA or the most recent CLSI interpretive criteria for reporting susceptibility results. Furthermore, we urge the FDA to positively consider submissions from device manufacturers that include an assessment of device performance for 510(k) clearance using current CLSI interpretive criteria, as well as the FDA drug label criteria in those few instances where differences exist. Acceptance of these recommendations will permit laboratories to detect antimicrobial resistance more effectively and guide antimicrobial therapy more appropriately.

Sincerely,

Ruth L. Berkelman, M.D.  
Chair, Public and Scientific Affairs Board  
American Society for Microbiology

Joseph M. Campos, PhD, DABMM, FAAM  
Chair, Committee on Laboratory Practices  
Public and Scientific Affairs Board, ASM

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