



# Society of Infectious Diseases Pharmacists

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September 11, 2006

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: Docket Item #2006P-0348

Dear Sirs:

The Society of Infectious Diseases Pharmacists (SIDP) is pleased to provide this letter in full support of the above mentioned citizen's petition submitted by the Clinical and Laboratory Standards Institute (CLSI) requesting that CDER amend the minimal inhibitory concentration indicative of susceptibility to vancomycin from 4 mg/L or less to 2 mg/L or less, that the intermediate category range be lowered from 8-16 mg/L to 4-8 mg/L, and that the resistance category definition be lowered from 32 mg/L or greater to 16 mg/L or greater. It is our shared belief that in light of the growing prevalence of bacterial pathogens, particularly *Staphylococcus aureus*, with higher vancomycin MIC values, such a change will provide better guidance to clinicians who consider vancomycin therapy for the management of specific infections, and thus improve the quality of care provided to their patients.

SIDP is a dynamic association of over 450 clinical pharmacists and other health professionals dedicated to excellence in infectious diseases pharmacotherapy and the appropriate use of antimicrobials. Our members are active across the country in the development of new knowledge through antimicrobial research from the bench to the bedside, the provision of quality patient care services in individual health care settings and for large health services organizations, and the education of patients and clinicians aimed at optimal antimicrobial use. In the performance of these important activities, we work closely with physicians, microbiologists, epidemiologists, nurses, and administrators to ensure that the critical aspects of infectious diseases pharmacotherapy are addressed in a timely and efficient manner.

Thank you for the opportunity to offer our support of this petition and for your consideration of our request.

Respectfully,

Thomas C. Hardin, Pharm.D., MBA, FCCP  
President  
Society of Infectious Diseases Pharmacists

Cc: SIDP Board of Directors

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