



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 24, 2006

**FILE COPY**

Robert Habig, PhD and Glen Fine, MS, MBA  
Clinical and Laboratory Standards Institute  
940 West Valley Road  
Wayne, PA 19087

Dear Dr. Habig and Mr. Fine:

Your petition requesting the Food and Drug Administration to amend the vancomycin HCl package insert to reflect modifications of the antimicrobial susceptibility interpretive criteria to better recognize emerging resistance resulting in compromised patient outcomes was received by this office on 08/23/2006. It was assigned docket number 2006P-0348/CP 1 and it was filed on 08/24/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in black ink, appearing to read "Lyle B. Jaffe".

Lyle B. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2006P-0348

ACK 1