



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 14 2007

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

Re: Docket No. 2006P-0348/CP1

Dear Dr. Habig and Mr. Fine:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 23, 2006. Your petition requests that FDA amend the package insert for vancomycin hydrochloride by revising the antimicrobial susceptibility interpretive criteria for *Staphylococcus aureus*.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0348

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