



June 18, 2007

FILE COPY

Robert Habig, PhD, President
Glen Fine, MS, MBA, Executive Vice President
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 clear new susceptibility test devices or modification of existing devices using CLSI interpretive breakpoints in those instances when the approved drug label of an agent contains incomplete or out of date information regarding susceptibility testing, was received by this office on 06/08/2007. It was incorrectly assigned docket number 2000D-0109/CP1 and it was filed on 06/08/2007. The correct docket number is 2007P-0237/CP 1. 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,

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

2007P-0237

ACK 1



June 11, 2007

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Glen Fine, MS, MBA, Executive Vice President
Clinical and Laboratory Standards Institute
940 West Valley Road
Wayne, PA 19087

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Sincerely,

Lyle D. Jaffe
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2000D-0109

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