



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

1002 7 JAN 10 P1:36
December 22, 2006

• Dr. Robert Habig, President
Mr. Glen Fine, Executive Vice President
Clinical and Laboratory Standards Institute
940 West Valley Road
Wayne, Pennsylvania 19087

Re: Citizen Petition, 2006P-0271

Dear Dr. Habig and Mr. Fine:

This is an interim response to your petition dated June 21, 2006, which was filed by the Food and Drug Administration (FDA) on June 26, 2006. In your petition you requested that (1) "applications for clearance to market medical devices used to determine the *in vitro* antimicrobial susceptibility of bacterial and fungal pathogens give positive consideration to use of new or revised susceptibility interpretive criteria advocated by Clinical Laboratory Standards Institute ..., as well as the interpretive criteria in the FDA-approved labels of antimicrobial agents that can be tested by the device"; and (2) the "application for clearance of fluconazole disks for disk diffusion susceptibility testing of *Candida* spp. be positively reviewed in order to allow rapid, inexpensive testing of *Candida* spp. patient isolates by clinical laboratories."

We are continuing to review the issues presented in your petition and are almost ready to issue a final response at this time. However, because of the Thanksgiving and end of the year holidays, it will unfortunately, take us just a little more time to receive all the clearances from both centers involved and the Office of the Commissioner. We expect to issue a final response early in 2007.

If you have any questions about this interim response, please contact Annette Marthaler at (240) 388-6312 or me at (301) 827-5709.

Sincerely yours,

Murray M. Lumpkin, M.D.
Deputy Commissioner for International
and Special Programs

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Bcc: HF-3
HFD-1
HFZ-440 (Selepak)
HFZ-440 (Gutman)
HFZ-001 (Marthaler)
HF-40 (Russ)

CDRH/OIVD, CDER, and OGC reviewed and cleared by email 12/20/2006.
Reviewed with minor edits: Wanda Russ: HF-40: 12/21/06
Sent to Dr. Lumpkin for r/c on 12/21/06.
Cleared by Dr. Lumpkin with additional language on 12/22/06. (Autopen per Dr. Lumpkin's email)