DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

AUG 13 2013

Edward J. Pardon
Merchant & Gould
10 East Doty Street, Suite 600
Madison, WI 53703-3376

Re: Docket No. FDA-2013-P-0203

Dear Mr. Pardon:

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 February 19, 2013. Your petition requests that FDA consider a proposed formulation of Voriconazole for Injection 200 mg/vial as appropriate for an Abbreviated New Drug Application submission, even though the proposed formulation contains an inactive ingredient that differs from the Reference Listed Drug by means other than preservative, buffer, or antioxidant.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

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