



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

February 19, 2013

FILE COPY

Edward J. Pardon
Merchant & Gould P.C.
10 E. Doty Street, Suite 600
Madison, WI 53703

Dear Mr. Pardon:

Your petition to the Food and Drug Administration on behalf of a client requesting action to be taken as outlined in the petition relating to the proposed formulation for drug product Vfend® I.V. (Voriconazole) for injection 200mg/Vial as appropriate for an Abbreviated New Drug Application (ANDA) submission, was received by this office on 2/19/2013. It was assigned docket number FDA-2013-P-0203/CP1, and it was filed on 2/19/2013. 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, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)