

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTIVIRAL DRUGS ADVISORY COMMITTEE MEETING

QUESTIONS TO THE COMMITTEE

October 4, 2001

The Town Center Hotel –Silver Spring, Maryland

NDA 21-266, Vfend™ (voriconazole) Tablets and NDA 21-267, Vfend™ I.V. (voriconazole) for Injection, Pfizer Global Research and Development, proposed for the treatment of invasive aspergillosis, serious *Candida* infections, infections caused by *Scedosporium* spp. and *Fusarium* spp., rare and refractory infections, and empirical antifungal therapy in febrile neutropenic patients.

1. Is there sufficient information to support that voriconazole is safe and effective for the treatment of invasive aspergillosis?

If not, what additional information would be needed to support this indication?

2. Is there sufficient information to support that voriconazole is safe and effective for empiric antifungal therapy in febrile neutropenic patients?

If not, what additional information would be needed to support this indication?

3. What additional phase 4 studies would you recommend?
4. What additional advice does the committee have regarding the design of future studies needed in the development of therapeutic agents for the initial therapy, and therapy of patients refractory or intolerant to other antifungal therapies, in patients with pulmonary and/or disseminated aspergillosis?