

## MEMORANDUM

**DATE:** October 1, 2001

**TO:** Advisory Committee Members and Guests

**FROM:** Voriconazole Review Team

**THROUGH:** Renata Albrecht, M.D.  
Acting Director  
Division of Special Pathogen and Immunologic Drug Products

**SUBJECT:** **Errata for Background Package for NDA 21-266 and 21-267:  
Voriconazole Tablets and Voriconazole for injection**

---

### Page 14:

Pharmacology/Toxicology section  
Liver tumors:

“In mice, 24-month oral administration of voriconazole at **50mg/kg...**” should read

“In mice, 24-month oral administration of voriconazole at **100mg/kg...**”

“In rats, there was an increase in hepatocellular adenomas in high dose females.” should read

“In rats, there was an increase in hepatocellular adenomas **in females treated at 50mg/kg.**”

### Page 15:

Teratogenicity:

“At doses as low as **1mg/kg** (equivalent to a human dose of **0.2 mg/kg...** should read

“At doses as low as **10mg/kg** (equivalent to a human dose of **2 mg/kg..**”

### Page 24:

Table 1: Under study 150-228 for rifabutin Cmax at 350 mg bid, the upper 90% CI given as **5%** should be changed to **105%**.

---

**Renata Albrecht, M.D.**  
**Acting Division Director**  
**Division of Special Pathogen and Immunologic Drug Products**