



## FILE COPY

November 19, 2004

Molly Rapp  
Ben Venue Laboratories  
300 Northfield Road  
Bedford, Ohio 44146

Dear Ms. Rapp:

Your petition requesting the Food and Drug Administration to determine that an additional dosage of Terbutaline Sulfate Injection, USP 1 mg/mL 25 mL Pharmacy Bulk, is suitable for evaluation under an ANDA, was received by this office on 11/19/2004. It was assigned docket number 2004P-0518 and it was filed on 11/19/2004. 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,

Jennie Butler, Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2004P-0518

ACK1