



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 27, 2001

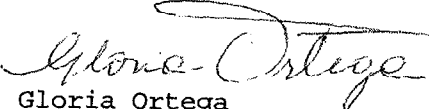
Molly Rapp
Ben Venue Laboratories, Inc.
300 Northfield Road
Bedford, OH 44146

Dear Ms. Rapp:

Your petition requesting the Food and Drug Administration to seek a determination that Ganciclovir Sodium Injection, 500mg/10mL, in a ready to use solution for injection is suitable for submission as an abbreviated new drug application (ANDA), was received by this office on 09/27/01. It was assigned docket number 01P-0440/CP 1 and it was filed on 09/27/01. 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,


Gloria Ortega
Dockets Management Branch

01P-0440

ACK 1