



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-458

Food and Drug Administration  
Rockville MD 20857

FEB 16 2006

Bedford Laboratories  
Attention: Molly Rapp  
Associate Director, Ben Venue Labs, Inc.  
300 Northfield Road  
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 20, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ranitidine Injection USP, 25 mg/mL, packaged in 1000 mg/40 mL vials (Pharmacy Bulk Package).

Reference is also made to your amendments dated August 24, and September 12, 2005; and January 12, and January 31, 2006.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Ranitidine Injection USP, 25 mg/mL, (Pharmacy Bulk Package) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, (Zantac<sup>®</sup> Injection 25 mg/mL, (Pharmacy Bulk Package) of GlaxoSmithKline.

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with

applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert [unclear] for". The signature is written in a cursive style with a large initial "R" and a long, sweeping underline.

Gary Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research