



APR. 19. 2006 2:38PM

FDA OGD CHEM3

NO. 100 P. 2

## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

ANDA 77-563

Food and Drug Administration  
Rockville MD 20857

APR 19 2006

Jubilant Pharmaceuticals, Inc.  
Attention: Rajan Enbran  
Director, Regulatory Affairs  
207 Kiley Drive  
Salisbury, MD 21801

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 3, 2005, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cyclobenzaprine Hydrochloride Tablets USP, 5 mg and 10 mg.

Reference is also made to your amendments dated May 27, June 3, and December 15, 2005; and February 14, and March 10, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Cyclobenzaprine Hydrochloride Tablets USP, 5 mg and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Flexeril Tablets, 5 mg and 10 mg, respectively, of McNeil Consumer and Specialty Pharmaceuticals). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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

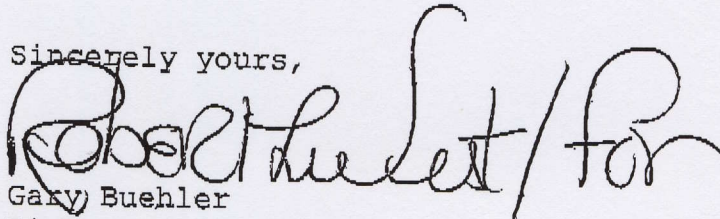
Post-marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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 dark ink, appearing to read "Robert L. Buehler" followed by a large, stylized flourish that resembles a large "R" or "B".

Gary Buehler  
Director

Office of Generic Drugs  
Center for Drug Evaluation and Research