DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 77-391

JAN 26 2006

Mylan Pharmaceuticals Inc.
Attention: S. Wayne Talton
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504

Dear Sir:

This is in reference to your abbreviated new drug application dated November 19, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Alprazolam Extended-release Tablets, 0.5 mg, 1 mg, 2 mg, and 3 mg.

Reference is also made to your amendments dated February 15, March 9, April 19, July 1, August 30, October 12, November 17, November 21, December 2, December 6, December 20, 2005 and January 17, 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 Alprazolam Extended-release Tablets 0.5 mg, 1 mg, 2 mg, and 3 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Xanax XR® 0.5 mg, 1 mg, 2 mg, and 3 mg Tablets of Pharmacia and Upjohn).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

The dissolution testing should be conducted using the FDA recommended method (Apparatus I (b)(4) with (b)(4) of a 1% phosphate buffer at a pH of 6.0 and at 37°C) using the USP (b)(4) at (b)(4) rpm.

0.5 mg tablets

Time (hours)	% Dissolved
1 hour	(b)(4)
4 hours	
8 hours	

1 mg tablets

Time (hours)	% Dissolved
1 hour	(b)(4)
4 hours	
8 hours	

2 mg tablets

Time (hours)	% Dissolved
1 hour	(b)(4)
4 hours	
8 hours	
16 hours	

3 mg tablets

Time (hours)	% Dissolved
1 hour	(b)(4)
4 hours	
8 hours	
16 hours	

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement - Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

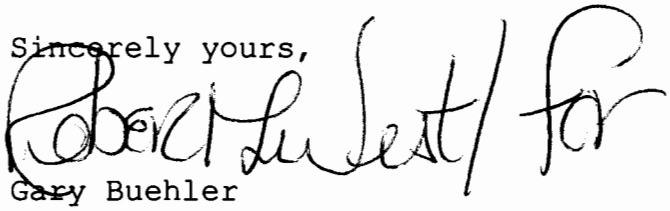
Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, 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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the drug application has been approved. You have agreed to submit 18 months stability data for your drug product. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response". To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE".

Sincerely yours,



Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research