ANDA 75-108 December 17, 1999

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application dated April 7, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nifedipine Extended-release Tablets, 30 mg.

Reference is also made to our tentative approval letter dated March 15, 1999, and to your amendments dated December 8, 1997; and June 1, October 14, and December 3, 1999.

The listed drug product (RLD) referenced in your application, Procardia XL Tablets, 30 mg, of Pfizer Laboratories, is subject to periods of patent protection which expire on November 25, 2000 (U.S. Patent No. 4,327,725), September 16, 2003 (U.S. Patents 4,612,008, 4,765,989, and 4,783,337), and November 23, 2010 (U.S. Patent No. 5,264,446, the ‘446 patent). Your application contains a patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, sale, offer for sale or importation of Nifedipine Extended-release Tablets, 30 mg, will not infringe on any of these patents, or that the patents are invalid, unenforceable, or will not be infringed. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated new drug application shall be made effective immediately unless an action is brought before the expiration of forty-five (45) days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the Agency that Mylan Pharmaceuticals, Inc. (Mylan) has complied with the requirements of Section 505(j)(2)(B) of the Act, and that a patent infringement suit involving the‘446 patent was initiated against Mylan in the United States District Court for the Western District of Pennsylvania (Bayer AG, Bayer Corporation and Pfizer Inc. v. Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc., Civil Action No. 97-1309).

You have also advised the Agency that the 30-month period provided for under section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice by the NDA and patent holders as required under section 505(j)(2)(B)(i) of the Act expired on December 16, 1999.

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 Nifedipine Extended-release Tablets, 30 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Procardia® XL Tablets, 30 mg, of Pfizer Laboratories).

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

> The dissolution testing should be conducted in 250 mL of SGF, with 0.25% TWEEN 80 for the first hour; then 250 ml of 0.01M phosphate buffer, pH 6.8 with 0.25% TWEEN 80 between 2 and 24 hrs, both at 37°C using USP Apparatus (III) at 20 dpm. The test product should meet the following tentative specifications:
>
> | | |
> |---|---|
> | 1 hr | [ ] |
> | 2 hrs | [ ] |
> | 8 hrs | [ ] |
> | 12 hrs | [ ] |
> | 24 hrs | [ ] |

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. A “Special Supplemental-Changes Being Effected” (zero) should be submitted if no revisions to the interim specifications are proposed or if the final specifications are tighter than the interim specifications. In all other instances a Prior Approval supplement should be submitted.

Under Section 506(A) of the Act, certain changes in the conditions described in this abbreviated application require

an approved supplemental application before the change may be made.

Post-marketing 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.
We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research