

ANDA 75-289/S-001

February 6, 2001

Keller and Heckman  
Attention: John Dubeck  
U.S. Agent for Biovail Laboratories Incorporated  
1001 G Street N.W., Suite 500 West  
Washington, D.C. 20001

Dear Sir:

This is in reference to your supplemental new drug application dated February 5, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Nifedipine Extended-release Tablets USP, 30 mg and 60 mg.

Reference is also made to the letter issued September 27, 2000. That letter granted final approval for your 60 mg strength only. As described in that letter, another ANDA for Nifedipine Extended-release Tablets USP, 30 mg, which contained a Paragraph IV certification to the patents for the listed drug was accepted for filing prior to the filing of the Biovail ANDA for the 30 mg strength. Therefore, on September 27, 2000, your ANDA was tentatively approved with respect to the 30 mg strength, pending the expiration of any 180-day exclusivity under Section 505(j)(5)(B)(iv) of the Act barring final approval. There is no longer a 180-day exclusivity bar to approval of your 30 mg strength product. For a complete discussion of the 180-day exclusivity issues with respect to Nifedipine Extended-release Tablets USP, 30 mg, please refer to the Citizen Petition and Petition Response at Docket No. 00P-1446/CP1.

This supplemental application, submitted as a "Prior Approval Supplement", provides for the full approval of the 30 mg strength.

We have completed the review of this supplemental application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the supplemental application is approved. The Division of Bioequivalence has determined that your Nifedipine Extended-release Tablets USP, 30 mg, to be bioequivalent and therefore therapeutically equivalent to the listed drug (Procardia XL<sup>®</sup> 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:

**30 mg tablet**

Dissolution Apparatus/Method

Apparatus	USP rotating paddle method (Apparatus 2)
Rotation speed	100 rpm

[ ]

The test product should meet the following specification:

Time (hours)	Amount dissolved
[	]

For each dosage unit, add the corresponding amount released in [ ].

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 when there are no revisions to the interim specifications or when the final specifications are tighter than the interim specifications. In all other instances a Prior Approval supplement should be submitted.

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.

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,

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

Supplement APPROVAL - New Strength