ANDA 75-128

March 10, 2000

Elan Pharmaceutical Research Corporation
Attention: Roger Wayne Wiley
1300 Gould Drive
Gainesville, GA 30504

Dear Sir:

This is in reference to your abbreviated new drug application dated April 30, 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 your amendments dated August 24 and December 3, 1999 and January 6, 2000 and February 4, 2000.

The listed drug product referenced in your application is subject to periods of patent protection which expire June 8, 2008 and November 23, 2010, (Patent Nos. 4,892,741 and 5,264,446). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of nifedipine will not infringe on the patent or that the patent is otherwise invalid. You further informed the Agency that Bayer Corporation initiated a patent infringement suit against you in United States District Court for the Northern District of Georgia [Gainesville Division](Bayer AG and Bayer Corporation v. Elan Pharmaceutical Research Corporation), Civil Action No. 2:97-CV-0143-WCO).

The Agency also recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

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 (Adalat® CC Extended-release Tablets of Bayer Corporation). 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 900 mL of de-ionised water containing 1.25% SLS at 37° C using USP Apparatus 2 (paddle) at 100 rpm. The test product should meet the following tentative specifications:

Time Points	% Released
[	]
[	]
[	]
[	]

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 Supplement - 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