

ANDA 75-128

May 28, 1999

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 July 30, 1997; and October 23, 1998 and April 12, 1999.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug product is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Adalat CC Extended-release Tablets of Bayer Corporation, is subject to periods of patent protection which expire on June 8, 2008, (U.S. Patent No. 4,892,741) and November 23, 2010, (U.S. Patent No. 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 this drug product will not infringe on either of the patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action for patent infringement is brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by both the referenced new drug application (NDA) and

patent holders. You have notified the Agency that Elan Pharmaceutical Research Corporation (Elan) has complied with the requirements of Section 505(j)(2)(B) of the Act and that the patent and NDA holders initiated a patent infringement suit against Elan in the 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). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,
 - b. the date of court decision [505(j)(5)(B)(iii) (I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,
 - c. the patents have expired, and
2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, please submit an amendment at least 60-days but not more than 90-days prior to the date you believe your application will be eligible for final approval. This amendment should be designated clearly in your cover letter as a MINOR amendment and it should identify the circumstances which have occurred that affect the effective date of final approval. The amendment must also provide:

1. a copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information, and
2. a. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

- b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

In addition to, or instead of, the amendments referred to above; the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above. Failure to submit these amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list, commonly referred to as the "Orange Book".

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Kassandra Sherrod, Project Manager, at (301) 827-5849, for further instructions.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for
Pharmaceutical Science
Center for Drug Evaluation and Research