

SEP 15 1997

Andrx Pharmaceuticals, Inc.
Attention: David A. Gardner
4001 S. W. 47th Avenue, Suite 201
Fort Lauderdale, FL 33314

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Dear Sir:

This is in reference to your abbreviated new drug application dated September 22, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Diltiazem Hydrochloride Extended-release Capsules USP, 120 mg, 180 mg, 240 mg and 300 mg.

Reference is also made to your amendments dated March 25, May 2, August 22, October 8, 1996; February 27, March 10, March 19, May 28 and June 20, 1997.

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 your application is **tentatively approved**. This determination is contingent upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is, therefore, 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)(4)(B)(iv) of the Act.

The listed drug product referenced in your application is subject to a period of patent protection which expires on May 20, 2011 [Patent No. 5,470,584]. However, litigation is underway in the United States District Court for the Southern District of Florida-Miami, involving a challenge to the patent (Hoechst Marion Roussel, Inc. and Carderm Capital L.P., v. Andrx Pharmaceuticals, Inc., Civil Action No. CIV 96-06121). Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(4)(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)(4)(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 patent has 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, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. Your amendment must 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 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 either or both 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, these drug products will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

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

Sincerely yours,



9/12/97

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