ANDA 75-456 (Carpuject)
ANDA 75-458 (Vials, 1 mL & 2 mL)

October 29, 1999

Abbott Laboratories
Attention: Jill N. Sackett
200 Abbott Park Road; D-389, Bldg. AP30
Abbott Park, IL 60064-6157

Dear Madam:

This is in reference to your abbreviated new drug applications dated September 4, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Enalaprilat Injection, 1.25 mg/mL.

Reference is also made to your amendment to each application dated August 6, 1999.

We have completed the review of these abbreviated applications and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the applications are tentatively approved. This determination is based upon information available to the Agency at this time, (i.e., data in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacturing and testing of the drug product), and is subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your applications, Vasotec I.V. Injection of Merck Research Laboratories, is currently subject to a period of patent protection (U.S. Patent No. 4,374,829). Your applications contain a Paragraph III Certification to the ‘829 patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market these drug products prior to the expiration of this patent. Therefore, final approval of your applications may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the patent has expired, i.e., February 22, 2000.

To provide for final approval of these applications, please

submit an amendment to each application at least 60 (but not more than 90) days prior to February 22, 2000. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. The amendments should be designated clearly as MINOR AMENDMENTS in your cover letter. In addition to or instead of these amendments, the Agency may request that you submit an amendment containing the same information at any time prior to the final date of approval.

Failure to submit such amendments requested by the agency will prompt a review of the applications which may result in rescission of this tentative approval letter or result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in these abbreviated applications as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the applications will be made.

Please note that this drug product 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 product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to February 22, 2000, you should amend your applications accordingly.

At the time you submit any amendments, you should contact Bonnie McNeal, Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

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

TENTATIVE APPROVALS