ANDA 75-240

November 27, 1998

Abbott Laboratories
Hospital Products Division
Attention: Jean Conaway
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-3537

Dear Madam:

This is in reference to your abbreviated new drug application dated October 31, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Labetalol Hydrochloride Injection USP, 5 mg/mL (Multiple Dose Vials).

Reference is also made to your amendments dated November 25, 1997, and June 5, August 25, October 13, November 19, and November 20, 1998.

We have completed the review of this abbreviated application 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 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 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.

The listed reference drug product upon which you have based your application is subject to a period of patent protection and final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(4)(B)(ii) of the Act until the period has expired, i.e., November 28, 1999.

Please provide the Agency, at least 60, but not more than 90, days prior to November 28, 1999, an amendment to this application. 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. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant changes in the conditions outlined in this abbreviated application requires Agency approval before the changes may be made effective.

Prior to issuance of a final approval letter by the Agency, your 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, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to November 28, 1999, you should amend your application accordingly.

At the time you submit any amendments, you should contact Mark Anderson, Project Manager, at (301) 827–5849, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 331(d).

Sincerely yours,

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