DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 10-515/S-022

MAY 4 1999

Abbott Laboratories
Attention: Ms. Jean Conaway
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Conaway:

Please refer to your supplemental new drug application dated December 31, 1997, received January 5, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Isuprel (isoproterenol hydrochloride) Injection.

We acknowledge receipt of your submissions dated February 5 and April 9, 1999. Your submission of April 9, 1999 constituted a complete response to our September 15, 1998 action letter.

This supplemental new drug application provides for final printed labeling revised as required in the December 13, 1994 Federal Register notice relating to the revision of the "Pediatric Use" subsection of the labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your April 9, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Gary Buehler
Regulatory Health Project Manager
(301) 594-5300

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research