CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 17-820/S-037

Approval Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-820/S-037

Eli Lilly and Company
Attention: Elizabeth C. Sloan, Pharm.D.
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Sloan:

Please refer to your supplemental new drug application dated August 27, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutrex Solution (Dobutamine Injection, USP).

We acknowledge receipt of your submissions dated March 26 and April 30, 2002. Your submission of April 30, 2002 constituted a complete response to our March 15, 2002 approvable letter.

This supplemental new drug application, as amended, provides for final printed labeling revised as follows:

1. Under **PRECAUTIONS**, a new **Geriatric Use** subsection was added that reads as follows:

   Of the 1893 patients in clinical studies who were treated with dobutamine, 930 (49.1%) were 65 and older. No overall differences in safety or effectiveness were observed between these and younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

   In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.

2. Under **DESCRIPTION**, the molecular structure, molecular formula, and molecular weight have been revised to reflect dobutamine hydrochloride and not dobutamine alone.

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 submitted final printed labeling (package insert included in your submission of April 30, 2002). 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. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C.Throckmorton M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton
7/23/02 12:30:56 PM