

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 17-820/S-037**

**Correspondence**



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 Ms. Sloan:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Dobutrex (dobutamine hydrochloride) Injection

NDA Number: 17-820

Supplement number: S-037

Date of supplement: August 27, 2001

Date of receipt: August 28, 2001

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 27, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products, HFD-110  
Attention: Division Document Room  
5600 Fishers Lane  
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Cardio-Renal Drug Products, HFD-110  
Attention: Division Document Room  
1451 Rockville Pike  
Rockville, Maryland 20852

If you have any questions, please call:

Mr. Edward Fromm  
Regulatory Project Manager  
(301) 594-5313

Sincerely yours,

A handwritten signature in black ink, appearing to read 'N. Morgenstern', written over a horizontal line.

Natalia A. Morgenstern  
Chief, Project Management Staff  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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

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Natalia Morgenstern  
9/13/01 03:02:08 PM