DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-201/S-013

Abbott Laboratories
Attention: Mr. Kenneth Oh
D-389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Dear Mr. Oh:

Please refer to your October 11, 2000 supplemental new drug application, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutamine in 5% Dextrose Injection in Polyester CR3 Flexible Container.

We also acknowledge receipt of your January 15, 2001 submission.

We note that this supplement was submitted as a "Special Supplement – Changes Being Effected" under 21 CFR 314.70(c).

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

1. Under **Description,** the last paragraph has been changed to:

   The flexible plastic container is fabricated from a specially formulated CR3 plastic material. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components form the plastic in very small amounts; however; biological testing was supportive of the safety for the plastic container materials. Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.

2. The package insert, overwrap and container labeling have been revised to emphasize visually the dobutamine name. In addition to the changed design and look of the labeling, the container and overwrap labeling have been revised as follows:

   (a). The statement "Usual dose: For I.V. Use. See Insert." has been replaced with "For I.V. Use. Usual Dosage: See Insert."
   (b). The statement "CAUTION: Federal (USA) Law prohibits dispensing without prescription" has been replaced with the "Rx Only" symbol (overwrap only).

We also note that there were several minor changes to the container and overwrap labeling.

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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 (package insert, container, and carton labels included in your submission dated October 11, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If you have any questions, please contact:

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

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
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