DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-099/S-008

B. Braun Medical Inc.
Attention: Ms. Susan Olinger
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your supplemental new drug application dated 4 May 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopamine Hydrochloride in 5% Dextrose Injection USP 200, 400, and 800 mg.

We acknowledge receipt of your submission dated 22 November 2004 which constituted a complete response to our 1 November 2004 approvable letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for final printed labeling revised as follows:

1. Under **PRECAUTIONS, General**, the second paragraph was relocated to **Laboratory Tests,** the content is unchanged.

2. Under **PRECAUTIONS,** a new subheading was added entitled: **"Geriatric Use"** incorporating the following language:

   Clinical studies of the dopamine HCL product did not include sufficient number of subjects aged 65 years and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. 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 other drug therapy.

3. The word **"children"** has been replaced with **"pediatric patients**" throughout the labeling.

4. Under **HOW SUPPLIED, Directions for Use** the following items were **deleted**:

   - The word **General**
   - Refer to Directions for Use for the administration set in use
   - **Products with Air Tube** section was deleted in its entirety
   - **Products with Solid Stopper**
   - Figures 2 and 3

5. The following **Administrative minor revisions** were noted:

    - Addition of a bar code to the front (first) page
    - "Rx only" was relocated from the last page under **HOW SUPPLIED** to the first page
    - "Made in the USA" was added under the **HOW SUPPLIED**
    - "Revised: May 1990" was updated to November 2004 under **HOW SUPPLIED**

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on 22 November 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call:

Cheryl Ann Borden, MSN, R.N., CCRN, CCNS
Regulatory Health Project Manager
(301) 594 5312.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., PhD.
Acting 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/

Norman Stockbridge

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