DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-615/S-014

Baxter Healthcare Corporation
Attention: Ms. Vicki Drews
1620 Waukegan Road MPGR-AL
McGaw Park, IL 60085

Dear Ms. Drews:

Please refer to your supplemental new drug application dated May 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopamine Hydrochloride in 5% Dextrose Injection, USP in Plastic Container, PL 2207, 0.8 mg/mL, 1.6 mg/mL, and 3.2 mg/mL.

We acknowledge receipt of your submissions dated December 6, 2000 and October 12, 2006. Your submission of October 12, 2006 constituted a complete response to our November 29, 2000 approvable letter.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section as follows:

> **Geriatric Use**
>
> Clinical studies of dopamine injection did not include sufficient numbers of subjects aged 65 and over 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.

In addition, the following changes were noted:

1. Throughout the package insert, “Viaflex®” has been changed to “VIAFLEX.”

2. The end of the package insert has been updated with the following information:

> ©Copyright 1985, 1989, 1994, 1995, Baxter Healthcare Corporation.
> All rights reserved.
> Baxter and VIAFLEX are trademarks of Baxter International Inc.
> 07-19-51-418
> Rev. Jul 2006

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on October 12, 2006.

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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal 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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