DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-615/S-017

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Route 120 and Wilson Road
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated March 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dopamine Hydrochloride and 5% Dextrose Injection, USP.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised to include changes to the package insert, immediate container, and overwrap labeling to differentiate better the packaging and labeling of your dopamine and dobutamine products. We note that upper case letters are used to designate the prefix "DOPamine" from "Dopamine" where appropriate to the package insert, immediate container and overwrap labels. We also note editorial and format changes to the immediate container and overwrap labels that enhance the safe use of this product.

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, immediate container and overwrap labels included in your submission of March 29, 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) 594-5313

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
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