



NDA 20-255/S-009 & S-011

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 applications dated September 19, 2001 (S-009) and May 8, 2003 (S-011), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutamine Hydrochloride in 5% Dextrose Injection, USP in Plastic Container, PL 2207

We acknowledge receipt of your submissions dated December 18, 2002 and April 24, 2003. Your submission of April 24, 2003 constituted a complete response to our July 3, 2002 action letter.

These "Changes Being Effected" supplemental new drug applications provide for 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 "DOBUTamine" from "Dobutamine" 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 intended to enhance the safe use of this product. Additionally, under **Description**, the last sentence of the section has been deleted and replaced with the following:

Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 24, 2003.

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 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
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/s/

Doug Throckmorton
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