DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-461/S-052

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Vice President, Regulatory Affairs
Route 120 and Wilson Road
RLT-10
Round Lake, IL 60073

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated June 27, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lidocaine HCl in 5% Dextrose Injection.

We acknowledge receipt of your submission dated July 11, 2003.

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

1. Under the **Description** section, the last sentence has been changed from:

   Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

   To:

   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 standards for plastic containers as well as by tissue culture toxicity studies.

2. Under **Contraindications**, the following has been added:

   Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products.

We have 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 June 27, 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. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

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

12/11/03 10:32:57 AM