DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-678/S-098 NDA 16-683/S-094
NDA 16-687/S-095 NDA 16-689/S-098
NDA 16-696/S-092 NDA 16-697/S-091

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Attention: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug applications dated March 2, 2004, received March 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dextrose in Sodium Chloride Injections in PL-146 Plastic Container.

NDA 16-678: 5% Dextrose in 0.9% Sodium Chloride Injections in Plastic Container PL-146
NDA 16-683: 5% Dextrose in 0.45% Sodium Chloride Injections in Plastic Container PL-146
NDA 16-687: 5% Dextrose in 0.33% Sodium Chloride Injections in Plastic Container PL-146
NDA 16-689: 5% Dextrose in 0.2% Sodium Chloride Injections in Plastic Container PL-146
NDA 16-696: 10% Dextrose in 0.9% Sodium Chloride Injections in Plastic Container PL-146
NDA 16-697: 2.5% Dextrose in 0.45% Sodium Chloride Injections in Plastic Container PL-146

These supplemental new drug applications provide for a revised **PRECAUTIONS** section. A **"Geriatric use"** subsection is added in accordance with the requirements of 21 CFR 201.57(f)(10).

We have completed the review of these supplemental applications and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling text for the package insert submitted on March 2, 2004. Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDAs 16-678/S-098, 16-683/S-094, 16-687/S-095, 16-689/S-098, 16-696/S-092, 16-697/S-091."** Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about any of these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to the respective NDAs and a copy to the following address:

MEDWATCH, HF-2
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, call Allison Meyer, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

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