DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-008/S-059
NDA 18-037/S-059
NDA 19-308/S-017

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 December 24, 1999, received December 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Potassium Chloride in 5% Dextrose and Sodium Chloride Injections in VIAFLEX Plus Plastic Container.

NDA 18-008: Potassium Chloride 10 mEq, 20 mEq, 30 mEq, and 40 mEq in 5% Dextrose and Sodium Chloride 0.45%
NDA 18-037: Potassium Chloride 10 mEq, 20 mEq, 30 mEq, and 40 mEq in 5% Dextrose and Sodium Chloride 0.2%
NDA 19-308: Potassium Chloride 10 mEq, 20 mEq, 30 mEq, and 40 mEq in 5% Dextrose and Sodium Chloride and 0.9%,

We acknowledge receipt of your submissions dated November 29, 2001.

These supplemental new drug applications provide for a revised **Pediatric Use** subsection of the **PRECAUTIONS** section of the package inserts.

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

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 NDA 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 Lisa Marie Malandro, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting 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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