DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-679/S-096

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 application dated November 11, 2003, received November 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lactated Ringer's and 5% Dextrose Injection in Plastic Container PL146.

Reference is also made to the May 3, 2004, telephone conversation between Mr. Mark Kopulos, Regulatory Associate, of your company and Ms. Parinda Jani of this Division.

This "Changes Being Effected" supplemental new drug application provides for a revised **ADVERSE REACTIONS** section of the package Insert.

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter.

As agreed to by Mr. Kopulos, you will continue submitting reports of allergic reactions or anaphylactoid symptoms as post-marketing 15-day safety alert reports.

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, call Ms. 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

5/12/04 11:34:26 AM