DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-677/S-124
NDA 16-682/S-092
NDA 16-693/S-084
NDA 17-378/S-055
NDA 17-438/S-051
NDA 18-016/S-049
NDA 19-022/S-017
NDA 19-047/S-018

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 February 13, 1998, received February 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA 16-677/S124	0.9% Sodium Chloride Injection in Plastic Container, PL 146®
NDA 16-682/S092	Lactated Ringer's Injection in Plastic Container, PL 146®
NDA 16-693/S084	Ringer's Injection in Plastic Container, PL 146®
NDA 17-378/S055	PLASMA-LYTE® 148 in Water in Plastic Container, PL 146® (Includes Plasma-Lyte® A)
NDA 17-438/S051	PLASMA-LYTE® Injection in Plastic Container, PL 146®
NDA 18-016/S049	0.45% Sodium Chloride in Water in Plastic Container, PL 146®
NDA 19-022/S017	3% and 5% Sodium Chloride Injections, USP in Plastic Container, PL 146®
NDA 19-047/S018	PLASMA-LYTE® 56 (Electrolyte Solution) in Plastic Container, PL 146®

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

Reference is also made to the March 1, 2002, teleconference between Ms. Linda Coleman, Senior Regulatory Manager, of your company, and Ms. Victoria Kao, Regulatory Project Manager, of this Division.

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.

As agreed to by Ms. Coleman the following statement of the DESCRIPTION section will be retained.

> "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 tissues culture toxicity studies."

The final printed labeling (FPL) must be identical, and include the editorial revisions indicated, to the submitted labeling (package insert submitted January 29, 2001) . These revisions are terms of the approval of this application. Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDAs 16-677/S-124, 16-682/S-092, 16-693/S-084, 17-378/S-055, 17-438/S-051, 18-016/S-049, 19-022/S-017, 19-047/S-018 etc." Approval of these submissions 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 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 Victoria Kao, Regulatory Project Manager, at (301) 827-7416.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, 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/

Cynthia McCormick
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