DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022

Baxter Healthcare Corporation
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085

Attention: Margarita Aguilera, M.S.
Director, Global Regulatory Affairs

Dear Ms. Aguilera:

Please refer to your supplemental new drug applications dated April 26, 2005, received April 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA Number	Name of Drug	Supplement Number
13-684	Osmitrol® Injection (Mannitol Injection, USP in Plastic Container)	092
16-677	0.9% Sodium Chloride Injection, USP in Plastic Container	139
16-678	5% Dextrose and 0.9% Sodium Chloride Injection, USP in Plastic Container	100
16-679	Lactated Ringer's and 5% Dextrose Injection in Plastic Container	099
16-682	Lactated Ringer's Injection, USP in Plastic Container	100
16-683	5% Dextrose and 0.45% Sodium Chloride Injection, USP in Plastic Container	096
16-687	5% Dextrose and 0.33% Sodium Chloride Injection, USP in Plastic Container	097
16-689	5% Dextrose and 0.2% Sodium Chloride Injection, USP in Plastic Container	100
16-692	M/6 Sodium Lactate Injection, USP in Plastic Container	091
16-693	Ringer's Injection, USP in Plastic Container	091
16-695	5% Dextrose in Ringer's Injection, USP in Plastic Container	093
16-696	10% Dextrose and 0.9% Sodium Chloride Injection, USP in Plastic Container	094
16-697	2.5% Dextrose and 0.45% Sodium Chloride Injection, USP in Plastic Container	093
17-378	PLASMA-LYTE® 148 Injection in Plastic Container [Includes PLASMA-LYTE® A Injection, pH 7.4]	063
17-385	PLASMA-LYTEV 56 In 5% Dextrose Injection In Plastic Container	055

17-390	PLASMA-LYTE® M in 5% Dextrose Injection I Plastic Container	060
17-438	PLASMA-LYTE Injection in Plastic Container	059
17-451	PLASMA-LYTE® 148 in 5% Dextrose Injection in Plastic Container	058
17-484	5% Dextrose with Electrolyte No. 48 in Plastic Container	062
17-634	5% Dextrose and Potassium Chloride Injections in Plastic Container	065
17-648	Sodium Chloride and Potassium Chloride Injections in Plastic Container	065
18-008	5% Dextrose, 0.45% Sodium Chloride and Potassium Chloride Injections in Plastic Container	065
18-016	0.45% Sodium Chloride Injection in Plastic Container	057
18-037	5% Dextrose, 0.2% Sodium Chloride and Potassium Chloride Injections in Plastic Container	065
18-840	5% Dextrose with Electrolyte No. 75 in Plastic Container	029
19-022	3% and 5% Sodium Chloride Injection, USP in Plastic Container	022
19-047	PLASMA-LYTE® 56 (Electrolyte Solution) in Plastic Container	024
19-308	Potassium Chloride in 5% Dextrose and 0.9% Sodium Chloride Injections in Plastic Container	022
19-367	Potassium Chloride in 5% Dextrose and Lactated Ringer's Injection in Plastic Container	022

We acknowledge receipt of your submissions dated June 23, August 15, 24 and 25, 2005.

These supplemental new drug applications provide for a new flexible polyolefin (non-PVC) container closure system.

We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We remind you of your agreement dated August 25, 2005, to revise the pH statement in the insert directions to read "The nominal pH is XX (XX to XX)."

The final printed labeling (FPL) for each product must be identical, and include the revisions indicated to the enclosed labeling text. These revisions are terms of the approval of these applications. 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 these submissions "**FPL for approved supplement** NDA 13-684/S-092, 16-677/S-139, 16-678/S-100, 16-679/S-099, 16-682/S-100, 16-683/S-096, 16-687/S-097, 16-689/S-100, 16-692/S-091, 16-693/S-091, 16-695/S-093, 16-696/S-094, 16-697/S-093, 17-378/S-063, 17-385/S-055, 17-390/S-060, 17-438/S-059, 17-451/S-058, 17-484/S-062, 17-634/S-065, 17-648/S-065, 18-008/S-065, 18-016/S-057, 18-

037/S-065, 18-840/S-029, 19-022/S-022, 19-047/S-024, 19-308/S-022, 19-367/S-022." Approval of these submissions by FDA is not required before the labeling for each product is used.

We remind you that the current expiry dating period should be maintained for each product until additional supporting stability data are provided to support new expiry dating periods.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Allison Meyer, Regulatory Project Manager, at (301) 827-7426.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

8/26/2005 03:50:00 PM