DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-451/S-060
NDA 17-378/S-065

Baxter Healthcare Corporation
Attn: Carey Anderson
Senior Director, Regulatory Affairs
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085

Dear Ms. Anderson:

Please refer to your supplemental new drug applications dated March 14, 2008, and March 21, 2008, received March 17, 2008, and March 21, 2008, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plasma-Lyte 148 and 5% Dextrose Injection in Plastic Container and Plasma-Lyte 148 Injection in Plastic Container (includes Plasma-Lyte A Injection pH 7.4).

We acknowledge receipt of your submissions dated March 19, 2008 for NDA 17-451/S-060 and March 21, 2008, March 24, 2008, and March 25, 2008 for NDA 17-378/S-065.

These "Changes Being Effected" supplemental new drug applications provide for the addition of Drug/Laboratory Test interactions safety information to the package insert.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 17-451/S-060, and NDA 17-378/S-065."

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 Cristi Stark, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (6)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
1/27/2009 05:41:29 PM
final recommendations based upon Micro Review July 29, 2008 and email correspondence from sponsor.