DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-840/S-028

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 application (NDA) dated December 6, 2004, received December 9, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 5% Dextrose and Electrolyte No. 75 Injection in Plastic Container, PL 146®.

This supplemental new drug application provides for a revised **PRECAUTIONS** section. A **"Geriatric Use"** subsection is added in accordance with the requirements of 21 CFR 201.57(f)(10).

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

As agreed to by you, the following information will be added to the **PRECAUTIONS: Geriatric Use** subsection.

> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may by useful to monitor renal function.

The final printed labeling (FPL) must be identical, and include the revisions indicated to the package insert submitted December 7, 2005. These revisions are terms of the approval of this application.

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 this submission "**FPL for approved NDA 18-840/S-028**." Approval of this submission by FDA is not required before the labeling is used.

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) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Division 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

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