DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-016 / S-053

Baxter Healthcare Corporation
Route 120 and Wilson Road; RLT-10
Round Lake, IL 60073

Attn: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated October 4, 2002, received October 7, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 0.45% Sodium Chloride Injection, USP in Plastic Container (PL 146®).

We acknowledge receipt of your submission dated March 14, 2003, which constituted a complete response to our February 6, 2003 action letter.

This supplemental new drug application provides for the addition of two new container sizes of 0.45% Sodium Chloride Injection, USP.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted with this amendment.

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 Lisa Malandro, Regulatory Project Manager, at (301) 827-7407.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Acting 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

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