DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19904/S-012

SUPPLEMENT APPROVAL

Baxter Healthcare Corp.
Attention: Amy Giertych
Senior Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Ms. Giertych:

Please refer to your Supplemental New Drug Application (sNDA) dated March 5, 2009, received March 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Highly Concentrated Potassium Chloride Injection (PL 146) in plastic container.

We acknowledge receipt of your amendments dated September 2, 2010 and September 8, 2011. The September 8, 2011, submission constituted a complete response to our October 19, 2009, action letter.

This "Prior Approval" supplemental new drug application provides for revised container and overwrap labels.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the revised container and overpouch labeling you submitted on September 8, 2011. These changes based on the Enhanced Labeling Usability Study to enhance the label include:

- Enhance label readability and consistent format
- Emphasize drug name
- Increase prominence to the total strength per total volume expression
- Increase white space

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on September 8, 2011, as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related

Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 19904/S-012**." Approval of this submission by FDA is not required before the labeling is used

REPORTING REQUIREMENTS

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

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

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/s/

JOYCE A KORVICK
03/14/2012