DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-321/S-009

Baxter Healthcare Corporation
Attention: Lisa M. Skeens, Ph.D.
Vice President, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085-6730

Dear Dr. Skeens:

Please refer to your supplemental new drug application dated June 9, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Extraneal (icodextrin) Peritoneal Dialysis Solution 7.5%.

We acknowledge receipt of your submission dated March 3, 2005 which constituted a complete response to our December 10, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides for the addition of the following statement to the **DESCRIPTION** section of the labeling:

> Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration dating period, e.g. di 2-ethylhexyl phthalate (DEHP), up to 5 parts per million; however, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed labeling (FPL) submitted on March 3, 2004

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, please contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I

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/

Norman Stockbridge

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