DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-321/S-017

Baxter Healthcare Corporation
Attention: Linda Coleman, R.A.C.
Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Ms. Coleman:

Please refer to your supplemental new drug application dated July 28, 2008 and received July 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Extraneal (icodextrin) 7.5% w/v peritoneal dialysis solution.

We also refer to your submissions dated January 23, February 24, and March 5, 2009. Your submission of March 5, 2009 constituted a complete response to our December 9, 2008 action letter.

Reference is also made to our action letter dated December 9, 2008 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Extraneal (icodextrin). This information pertains to the risk of hypoglycemia in patients receiving Extraneal (icodextrin) therapy and also inappropriately administered insulin therapy, based on falsely elevated blood glucose levels (due to the drug-device interaction with some non-glucose-specific glucometers).

Your supplemental application provides for revisions to the labeling for Extraneal (icodextrin). We agree with your proposed changes to the language included in our December 9, 2008 letter.

We have completed our review of this supplemental application, as amended. The application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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
Food and Drug Administration
Suite 12B05
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, please call Anna Park-Hong, Project Manager, at 301-796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures:
Agreed-upon labeling text
Medication Guide

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

4/7/2009 11:50:45 AM