DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-321/S-018

Baxter Healthcare Corporation
ATTTENTION: Linda Coleman, RAC
1620 Waukegan Road
McGaw Park, Illinois 60085

Dear Ms. Coleman:

Please refer to your Supplemental New Drug Application dated July 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EXTRANEAL (7.5% icodextrin) Peritoneal Dialysis Solution.

We acknowledge receipt of your submissions dated October 21, 2008 and January 19, 2009.

This supplemental new drug application provides for the use of an alternative luer lock closure with pull ring cap for Extraneal Solutions packaged in the Ambu-Flex Container Closure System. It also provides for revisions to the **DESCRIPTION, DOSAGE AND ADMINISTRATION** and **HOW SUPPLIED** sections of the labeling. We also note revisions to the container labels for the Ambu-Flex (b) (4) products.

We have completed our review of your labeling changes. It is approved, effective on the date of this letter, for use as recommended in the draft labeling submitted on January 19, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert submitted January 19, 2009**,** patient package insert submitted January 19, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-321/S-018."

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 call Anna Park-Hong, Regulatory 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

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

1/29/2009 03:47:45 PM