DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-321/S-013

Baxter Healthcare Corporation
Attention: Linda Coleman, RAC
Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085-6730

Dear Ms. Coleman:

Please refer to your supplemental new drug application dated August 18, 2006, 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 November 29, 2006.

This "Changes Being Effected" supplemental new drug application provides for labeling revised as follows:

1. The **WARNINGS** section has been changed from:

   Blood glucose measurement in patients receiving EXTRANEAL must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose, released from EXTRANEAL. Glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ)-based methods must not be used. The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose results. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP.

   To:

   Blood glucose measurement in patients receiving EXTRANEAL must be done with a glucose-specific method (monitor and test strips) to avoid interference by maltose, released from EXTRANEAL. Glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase based methods must not be used. If GDH-PQQ or glucose-dye-oxidoreductase based methods are used, using EXTRANEAL may cause a falsely high glucose reading, which could result in the administration of more insulin than needed. This can cause hypoglycemia, which can result in loss of consciousness, coma, neurological damage and death. Additionally, falsely elevated blood glucose measurements due to maltose interference may mask true hypoglycemia and allow it to go untreated with similar consequences.

   The manufacturer(s) of the monitor and test strips should be contacted to determine if icodextrin or maltose causes interference or falsely elevated glucose results. For a list of toll free numbers for glucose monitor and test strip manufacturers, please contact the Baxter Renal Clinical Help Line 1-888-RENAL-HELP.

2. Under **PRECAUTIONS/Information for Patients**, the fourth paragraph has been changed from:

Because the use of EXTRANEAL interferes with glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ)-based blood glucose measurements, diabetic patients should be instructed to use only glucose-specific glucose monitors and test strips (See **WARNINGS, PRECAUTIONS, Drug Laboratory Test Interactions**).

To:

Because the use of EXTRANEAL interferes with glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) and glucose-dye-oxidoreductase based blood glucose measurements, patients should be instructed to use only glucose-specific glucose monitors and test strips. (See **WARNINGS; PRECAUTIONS, Drug/Laboratory Test Interactions**).

3. Under **PRECAUTIONS/Drug/Laboratory Interactions/**Blood Glucose, references to glucose-dye-oxidoreductase have been added. The section now reads as follows:

   Blood glucose measurement must be done with a glucose-specific method to prevent maltose interference with test results. Since falsely elevated glucose levels have been observed with blood glucose monitoring devices and test strips that use glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase based methods, GDH PQQ or glucose-dye-oxidoreductase based methods should not be used to measure glucose levels in patients administered EXTRANEAL. (See **WARNINGS**).

4. In the patient package insert, references to glucose-dye-oxidoreductase have been added to the warning for patients who monitor their blood glucose. The section now reads as follows:

   If you monitor your blood glucose, you must use a glucose specific monitor and test strips. If your glucose monitor or test strips use a glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) or glucose-dye-oxidoreductase method, using EXTRANEAL may cause a falsely high glucose reading or may mask a very low actual glucose reading. A false high blood glucose reading could cause you to give more insulin than you need. Getting more insulin than you need can cause a serious reaction including loss of consciousness, coma, neurological damage and death. If you have true low blood sugar but are using a monitor that is not specific, you may inadvertently delay taking appropriate measures to correct the low blood sugar. YOU OR YOUR NURSE OR DOCTOR SHOULD CONTACT THE MANUFACTURER(S) OF THE MONITOR AND TEST STRIPS TO MAKE SURE THAT EXTRANEAL, ICODEXTRIN OR MALTOSE WILL NOT INTERFERE WITH THE TEST RESULTS.

5. The copyright information has been removed.

6. The item number and date have been revised.

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 final printed labeling (FPL) submitted on November 29, 2006.

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 contact:

Mr. Russell Fortney
Regulatory Health Project Manager
(301) 796-1068

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

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