



NDA 17512/S-122  
NDA 20163/S-027  
NDA 20183/S-026

**SUPPLEMENT APPROVAL**

Baxter Healthcare Corporation  
Attention: Jennifer Masek-Little  
Director, Global Regulatory Affairs  
32650 N. Wilson Road  
Round Lake, IL 60073

Dear Ms. Masek-Little:

Please refer to your Supplemental New Drug Applications (sNDAs) dated August 12, 2015, received August 12, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DIANEAL 1.5%, 2.5% and 4.25% Dextrose Peritoneal Dialysis Solution, DIANEAL ULTRABAG (Dianeal PD-2 Peritoneal Dialysis Solution with Dextrose), and, DIANEAL ULTRABAG (Dianeal Low Calcium Peritoneal Dialysis Solution with Dextrose), respectively.

These “Changes Being Effected” supplemental new drug applications provide labeling revisions as follows (additions are marked as underlined text and deletions are marked as strikethrough text):

1. Under DOSAGE AND ADMINISTRATION, the following text was added/deleted:  
**Administration instructions for CAPD therapy using ULTRABAG containers  
(Products listed in Tables 1-2)**

Put on mask. Clean and/or disinfect hands. Using aseptic technique;

1. Uncoil tubing and drain bag, ensuring that the transfer set is closed.
2. Immediately attach the solution container to patient connector (transfer set) ~~or appropriate automated peritoneal dialysis set.~~
3. Break the connector (Y-set) frangible.
4. Remove the tip protector from ~~the~~ connector of solution container. Do not reuse the solution or container once the tip protector is removed.
5. Clamp solution line and then break frangible near solution bag. Hang solution container and place the drainage container below the level of the abdomen.
6. Open transfer set to drain the solution from abdomen. If drainage cannot be established, contact your clinician. When drainage complete, close transfer set.
7. Remove clamp from solution line and flush new solution to flow into the drainage container for 5 seconds to prime the line. Clamp drain line after flush complete.

8. Open transfer set to fill. When fill complete, close transfer set.
  9. Disconnect ~~UltraBag~~ ULTRABAG from transfer set and apply ~~MiniCap~~ MINICAP.
  10. Upon completion of therapy, discard any unused portion.
2. Under DOSAGE AND ADMINISTRATION, the following text was added/deleted:  
**Administration instructions for APD therapy using containers with pull rings or blue pull tips (Products listed in Tables 3-5)**  
Put on mask. Clean and/or disinfect hands. Using aseptic technique;
    - 1) Remove the tip protector from connector of solution container. Do not reuse the solution or container once the tip protector is removed.
    - 2) Immediately attach the solution container to ~~patient connector (transfer set)~~ or an appropriate automated peritoneal dialysis set.
    - 3) Continue therapy as instructed in user manual or directions accompanying tubing sets for automated peritoneal dialysis.
    - 4) Upon completion of therapy, discard any unused portion.
  3. Under DOSAGE AND ADMINISTRATION, the following text was added/deleted:  
**Administration instructions for APD therapy using containers with blue twist-off tips (Products listed in Tables 6)**  
Put on mask. Clean and/or disinfect hands. Using aseptic technique;
    - 1) Place and fasten blue outlet port clamp on solution bag administration port, between the blue connector and the solution container.
    - 2) ~~Twist-off~~ Remove the blue twist-off tip from connector of solution container. Do ~~Once the blue twist-off tip has been removed do~~ not reuse the solution or container once the blue twist-off tip is removed.
    - 3) Immediately insert the spike of the automated peritoneal dialysis set into the solution bag port.
    - 4) Continue ~~with~~ therapy as instructed in user manual or directions accompanying tubing sets for automated peritoneal dialysis.
    - 5) Upon completion of therapy, discard any unused portion.
  4. Draft Container Labels for Castlebar and Cuernavaca products (updated to align with NDCs in the currently approved Dianeal package insert)
  5. Minor editorial changes throughout the label

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your August 12, 2015, submissions containing final printed carton and container labels.

Marketing the products with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **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, please call Anna Park, Regulatory Project Manager, at (301) 796-1129.

Sincerely,

*{See appended electronic signature page}*

Mary Ross Southworth, Pharm.D.  
Deputy Director of Safety  
Office of Drug Evaluation I

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Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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MARY R SOUTHWORTH  
09/01/2015