DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21321/S-028

SUPPLEMENT APPROVAL
REMS MODIFICATION NOTIFICATION

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

Dear Ms. Little:

Please refer to your Supplemental New Drug Application (sNDA) dated August 30, 2013, received September 3, 2013, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EXTRANEAL (icodextrin) Peritoneal Dialysis Solution.

We acknowledge receipt of your amendment dated November 14, 2014.

This "Prior Approval" supplemental new drug application provides for the revision to the drug product package insert for EXTRANEAL which has been reformatted to meet the requirements of FDA's Physician's Labeling Rule (PLR) per 21 CFR 201.56(d) and 201.57.

APPROVAL & LABELING

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

We note that your November 14, 2014, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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, Medication

Guide), 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).

MARKET PACKAGE

Please submit one market package of the drug product when it is available to the following address:

Anna Park
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 4156
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** *if shipping via United States Postal Service (USPS).*
Use zip code **20993** *if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT

The REMS for Extraneal (icodextrin) was originally approved on March 9, 2011, and a REMS modification was approved on February 25, 2014. The REMS consists of a Medication Guide, elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

In accordance with section 505-1(g)(4)(B) of the FDCA, we have determined that your approved REMS for Extraneal (icodextrin) must be modified so that the REMS materials reflect the revised labeling approved above and to ensure that the benefits of the drug outweigh its risks.

Your proposed REMS modification submission must include revisions to the following REMS materials to insert the revised Boxed Warning:

- EXTRANEAL PD Nurse Training Tool
- EXTRANEAL Patient Kit

The timetable for submission of assessments of the proposed modified REMS may remain the same as that approved on March 9, 2011.

The proposed REMS modification submission should include the REMS document and appended REMS materials that were approved on February 25, 2014 and the revised REMS materials described above.

In addition, the submission should include an update to the REMS supporting document that includes a description of all proposed modifications and any impact the proposed modifications would have on other REMS elements. Revisions to the REMS supporting document should be submitted with all changes marked and highlighted.

Because we have determined that a modified REMS with the elements described above is necessary to ensure the benefits of Extraneal (icodextrin) outweigh the risks, you must submit a proposed REMS modification within 30 days of the date of this letter, as a supplement to your NDA.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

NEW SUPPLEMENT FOR NDA 021321
PROPOSED REMS MODIFICATION

Prominently identify subsequent submissions related to the proposed REMS modification with the following wording in bold capital letters at the top of the first page of the submission:

NDA 021321
PROPOSED REMS MODIFICATION-AMENDMENT

If you do not submit electronically, please send 5 copies of your submission.

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

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}

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

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
12/09/2014