DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021321/S-029

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Jennifer Masek-Little
Associate Director
32650 North Wilson Road
Mailstop: WG2-3S
Round Lake, IL 60073

Dear Ms. Masek-Little:

Please refer to your Supplemental New Drug Application (sNDA) dated September 13, 2013, and received September 16, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Extraneal (icodextrin) 7.5% Solution for Peritoneal Dialysis.

We also refer to our REMS Modification Notification letter dated July 18, 2013. We acknowledge receipt of your amendments dated December 2, 2013, and January 30, 2014 and your risk evaluation and mitigation strategy (REMS) assessment dated March 7, 2013.

This supplemental new drug application provides for a proposed modification to the approved REMS.

APPROVAL

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Extraneal (icodextrin) was originally approved on March 9, 2011. 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 our REMS Modification Notification letter dated July 18, 2013, your proposed modification to the REMS consists of a revision of the approved REMS to include language to update the U.S. specific glucose monitor website (www.glucosesafety.com) every six months. You have also proposed a modification to update the REMS document and relevant appended materials to show a new address for Baxter Healthcare Corporation.

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

You have also revised the Extraneal REMS assessment plan to include reporting on the periodic updates to the glucose monitor website. The revised REMS assessment plan should include, but is not limited to, the following:

1. Number of EXTRANEAL units sold in the US during the reporting period;

2. Number of new patients in the US dispensed EXTRANEAL during the reporting period;

3. Number of and percentage of new patients who have received an EXTRANEAL Patient Kit during the reporting period;

4. Number of US dialysis clinics that have been trained during the reporting period;

5. Number and percentage of patients receiving EXTRANEAL whose dialysis clinics were not previously trained;

6. Summary of updates made to the U.S. country-specific glucose monitor list on www.glucosesafety.com;

7. Evaluation of patients' understanding of the safe use of EXTRANEAL, and receipt and understanding of the Medication Guide;

8. Evaluation of health care providers that train EXTRANEAL patients (i.e. PD Nurses) understanding of the safe use of EXTRANEAL, in particular, the drug-device interaction and the potential for falsely elevated blood glucose readings in patients using EXTRANEAL.

9. Status of safety data exchange agreements between Baxter and manufacturers of non-specific glucose monitoring systems;

10. A summary of adverse event reports for hypoglycemia related to drug-device interaction, including those resulting in hypoglycemic complications, and the root cause analysis. The root cause analysis will include: the case narrative, the device involved (if known), and information about the use and knowledge of communication tools by the patient involved in the adverse event and the responsible health care provider (if known);

11. A summary of any packaging process exceptions relating to Extraneal Medication Guide dispensing, including corrective actions taken to address noncompliance;

12. A description of the specific measures that will be taken to increase awareness, if we conclude during our Extraneal safety review that dialysis clinic and patient awareness of the drug-device interaction is not adequate;

13. With respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal, or whether one or more such goals or such elements should be modified [per section 505-1(g)(3)].

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of the FDCA.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted. Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 021321 REMS CORRESPONDENCE
(insert concise description of content in bold capital letters, e.g.,
UPDATE TO REMS SUPPORTING DOCUMENT - ASSESSMENT METHODOLOGY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 021321 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 021321
PROPOSED REMS MODIFICATION

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 021321
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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:

Lori Anne Wachter, RN, BSN, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
REMS

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

/s/

MARY R SOUTHWORTH
02/25/2014