DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18883/S-057
NDA 20171/S-039

SUPPLEMENT APPROVAL

Fresenius Medical Care North America
Attention: Claude Miller
Vice President, Regulatory Affairs
920 Winter Street
Waltham, MA 02451

Dear Mr. Miller:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 3, 2014, received July 3, 2014, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DELFLEX Peritoneal Dialysis (PD) Solutions (1.5%, 2.5% and 4.25% Dextrose with Standard Calcium/Standard Magnesium and with Standard Calcium/Low Magnesium) and for DELFLEX PD Solutions (1.5%, 2.5% and 4.25% Dextrose with Low Calcium/Low Magnesium).

We acknowledge receipt of your amendment dated December 10, 2014.

These "Changes Being Effected" supplemental new drug applications provide for updated shipping carton labels, in which the label part number was relocated from the right side of the label to immediately below the corresponding label part number barcode to reduce ambiguity as follows:

1. The text "DELFLEX" has been increased to improve readability of dextrose strengths.

2. The text "PERITONEAL DIALYSIS SOLUTION WITH" has been changed, bolded, and spanned across the label to improve readability.

3. The text "1.5% DEXTROSE" has been increased and the background has been shaded with the dextrose strength identification color.

4. The text "LOW MAGNESIUM" has been increased and relocated to the right side of the label.

5. The statement "W/CONELESS MED PORT" has been removed from the label because the statement is no longer necessary. The medicinal port was originally manufactured with a cone component that was later removed to create a coneless medicinal port on specific product lines.

6. The revision date has been reduced in font size from Arial size 12 to Arial size 6 and has moved to the right side of label.

7. "BOX CNT" at the bottom of the label has been shifted to the right side of the label and replaced with a barcode.

8. The font size of the strength e.g."1.5%" has been increased.

9. The NDC barcode has been moved to the bottom of the label and the font size of the NDC number has been changed and moved to be above the barcode.

10. The lot number ("LOT") barcode has been moved to the bottom of the label and "LOT" has been amended to "LOT NO".

11. The catalogue number ("CAT") barcode has been moved to the bottom of the label and "CAT." has been amended to "CAT. NO."

12. The quantity statement has been changed from "4-3000 ML UNITS" to "FOUR-3000 ML UNITS".

13. The font size of the expiration date ("EXP.") font has been changed.

14. The lot number ("LOT NO.") has been moved to the bottom of the label and the font size has been decreased.

15. The catalogue number ("CAT. NO.") has been moved to the bottom of the label from the top right and bottom. The catalogue number is only presented in one location on the label instead of being provided under a barcode and as a separate "CAT NO."

16. The manufacturer contact information (#17) has been added to the lower left part of the label.

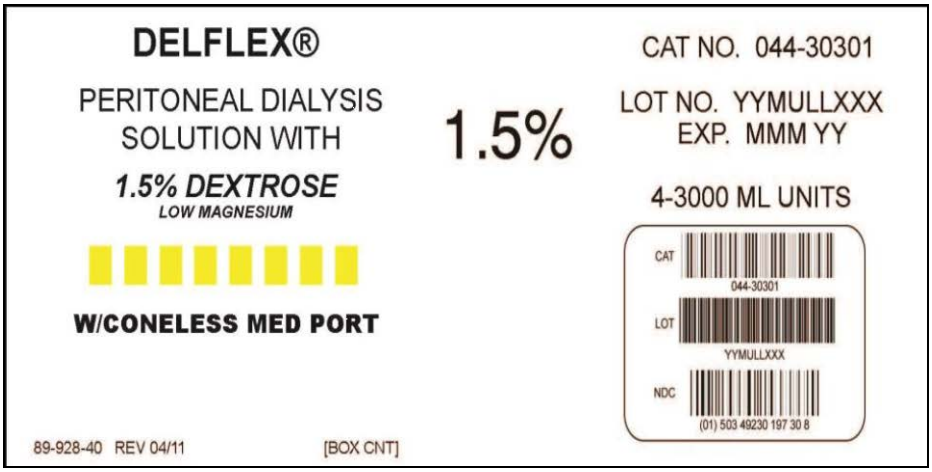
17. A barcode (#18) that corresponds to the label part number has been added.

18. There are five (5) **double bag** label examples covering various dextrose concentrations and fill size/bag sizes:
    1) Conventional pH-Low Mg/Low Ca
    2) Conventional pH-Low Mg/Standard Ca
    3) Neutral pH-Low Mg/Low Ca
    4) Neutral pH-Low Mg/Standard Ca
    5) Neutral pH-Standard Mg/Standard Ca

    And six (6) **single bag** label examples covering various dextrose concentrations and fill size/bag sizes:

1) Conventional pH-Low Mg/Low Ca
2) Conventional pH-Low Mg/Standard Ca
3) Conventional pH-Standard Mg/Standard Ca
4) Neutral pH-Low Mg/Low Ca
5) Neutral pH-Low Mg/Standard Ca
6) Neutral pH-Standard Mg/Standard Ca

An example of the label change, using the 1.5% strength, is:



To:

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS (SHIPPING CARTON LABELS)

We acknowledge your December 10, 2014, submission containing your draft shipping carton labels.

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).

We acknowledge receipt of your email, dated January 22, 2015, requesting amending the approval letter for the following reasons:

- On page 1, the second paragraph, the date should be December 10, 2014, not September 10, 2014.
- On page 4, under "Carton and Immediate Container Labels", we did not include carton and container labels in this submission, only Case labels. Also, we submitted draft labeling, but no final printed labeling.

We acknowledge the errors and the approval letter has been revised accordingly. The effective date of the action will remain the same as January 8, 2015, the date of the original action letter. Please note that this approval letter supersedes our original approval letter for this application.

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.
Director of Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Agreed-upon labeling text
Carton and Container Labeling (Shipping Carton Labels)

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
01/08/2015