**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**
**Silver Spring MD 20993**

NDA 018883/S-033
NDA 020171/S-015

**APPROVAL LETTER**

Fresenius Medical Care
Attention: Anila Mico, MS
920 Winter Street
Waltham, MA 02451-1457

Dear Ms. Mico:

Please refer to your supplemental new drug applications dated July 30, 2009, received July 31, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delflex Standard Magnesium and Low Magnesium (NDA 18-883) and Delflex Low Magnesium/Low Calcium (NDA 20-171) Peritoneal Dialysis (PD) Solutions.

We acknowledge receipt of your submissions dated March 23, June 17, 2009, August 19 and September 8 2009.

Your submission of June 17, 2009 constituted a complete response to our November 26, 2008 action letter.

These supplemental new drug applications provides for changes to the approved primary packaging to separate the (b) (4) component of the drug product formulation from other formulation ingredients until point of use and adjustment in pH of the final Delflex PD solution to (b) by using (b) (4) , USP as a buffering agent.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted on September 8, 2009 and immediate container and carton labels submitted June 17, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 018883/S-033 and NDA 020171/S-015."

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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

Enclosure: Agreed-upon labeling text

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-18883 | SUPPL-33 | FRESENIUS MEDICAL CARE NORTH AMERICA | DELFLEX W/ DEXTROSE 1.5% IN PLASTIUTION) |
| NDA-20171 | SUPPL-15 | FRESENIUS MEDICAL CARE NORTH AMERICA | DELFLEX W/ DEXTROSE 1.5% LOW MAGNESIUM L |

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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
09/14/2009