DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-910

Dialysis Solutions Inc.
Attention: Walter O'Rourke
14 Emmett Place
Whitby, Ontario
L1R 2B4 Canada

Dear Mr. O'Rourke:

Please refer to your new drug application (NDA) dated September 23, 2005, received September 26, 2005, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for NORMOCARB HF™ (NORMOCARB HF™ 25 and NORMOCARB HF™ 35).

We acknowledge receipt of your submissions dated March 28 and 31, May 15 and 31, June 12, and July 20, 2006.

This new drug application provides for the use of NORMOCARB HF™ (NORMOCARB HF™ 25 and NORMOCARB HF™ 35), after dilution, as a replacement solution in Continuous Renal Replacement Therapy (CRRT) to replace water and to correct electrolytes and acid-base imbalances in adults and children.

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

The final printed labeling (FPL) must be identical to the enclosed labeling and immediate container and carton labels submitted July 21, 2006. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved new drug.

1. Please note the minor change under **DOSAGE AND ADMINISTRATION**:

   Phosphate: Potassium phosphate up to 1.2 mMol/L (2.4 mEq/L) may be added to the diluted solution. The total potassium concentrate should not exceed 4 mEq/L.

   to

   Phosphate: Potassium phosphate up to 1.2 mMol/L (2.4 mEq/L) may be added to the diluted solution. The total potassium concentration should not exceed 4 mEq/L.

Please submit an electronic version of the FPL. The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The

guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, designate this submission "**FPL for approved NDA 21-910**." Approval of this submission by FDA is not required before the labeling is used.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Ms. Dianne Paraoan, 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: Agreed-upon Labeling Text

cc: ViCRO LLC
Dr. Ann Rose
U.S. Agent
2600 Pennsylvania Ave., #80
Washington, DC 20037

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

/s/

Norman Stockbridge

7/26/2006 09:55:51 AM