DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-703

Gambro Renal Products
Attention: Fei Law
Quality and Regulatory Manager, US
1845 Mason Avenue
Daytona Beach, FL 32117

Dear Ms. Law:

Please refer to your new drug application (NDA) dated September 27, 2005, received September 28, 2005, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for PrismaSol Solutions (BK 0/3.5, BGK 2/0, BGK 2/3.5, BGK 4/3.5, BGK 4/2.5, BGK 4/0, BK 4/2.5, BGK 0/2.5, and BK 0/0).

We acknowledge receipt of your submissions dated December 5, 2005, and April 7 and 28, June 22, July 7, September 22 (two) and 29, October 10, 11, 23, and 24, 2006.

This new drug application provides for the use of PrismaSol Solutions (BK 0/3.5, BGK 2/0, BGK 2/3.5, BGK 4/3.5, BGK 4/2.5, BGK 4/0, BK 4/2.5, BGK 0/2.5, and BK 0/0) as replacement solutions in Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by ultrafiltration and to correct electrolytes and acid-base imbalances in adults and children. PrismaSol solution may also be used in case of drug poisoning when CRRT is used to remove filterable substances.

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 submitted labeling (package insert submitted and immediate container and carton labels submitted October 23, 2006). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the products misbranded and unapproved new drugs.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-703**." Approval of this submission by FDA is not required before the labeling is used.

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 these products. 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 Health Project Manager
(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: Ms. Melanie Baviere
Gambro SAS
1/3 bld Charles de Gaulle
92707 Colombes Cedex
France

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

10/25/2006 01:00:49 PM