DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021703/S-008

SUPPLEMENT APPROVAL

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

Dear Ms. Law:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2009, received July 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PrismaSol Solutions (BK0/3.5, BGK 2/0, BGK 2/3.5, BGK4/3.5, BGK 4/2.5, BGK 0/2.5, BGK4/0, BK 4/2.5, BK0/0, B22GK2/0, B22GK4/0, B22GK2/2.5, B22GK4/2.5, BK0/0/1.2 and BGK4/0/1.2).

We acknowledge receipt of your amendments dated December 10, 2009, April 22, 2010, July 22, 2011, and March 19, 2012.

The July 22, 2011 submission constituted a complete response to our October 13, 2010, action letter.

This "Prior Approval" supplemental new drug application provides for implementation of FDA's new Physician Labeling Review (PLR) format.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Gambro Lundia AB
Attention: Ms. Melanie Baviere
PO Box 10 101
SE-220 10 Lund
Sweden

Enclosure: Labeling text

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

/s/

NORMAN L STOCKBRIDGE
04/13/2012