



NDA 021703/S-010

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 April 29, 2013, received April 30, 2013, 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 amendment dated May 13, 2013.

This "Changes Being Effected" labeling supplemental new drug application proposes a bag artwork improvement to PrismaSol's solution in PVC bag configuration to add and reinforce the user instructions on how to break the frangible pin and mix the small and large compartments. No changes have been made to the Package Insert labeling, just to the print of the PVC container.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter. Please submit final printed container labels that are identical to the enclosed immediate container label submitted on May 13, 2013, as soon as they are available, but no more than 30 days after they are printed.

Please consider following changes with your next labeling supplement.

Division of Medication Error Prevention Analysis (DMEPA)

1. Add a box graphic "Compartment B" on the top right corner of the large compartment, similar to the box graphic "Compartment A" for the smaller compartment, for consistency and clarity so users can easily differentiate the two compartments.
2. Ensure the two box graphics used to identify compartments A and B are identical in presentation, layout, and relative location. However, the placement of these two box

graphics may be at a different location from the proposed compartment A graphic location, if necessary, to accommodate all the changes on the bag label.

3. Increase the prominence of the “Break red pin and mix” and “Mix both compartments before use” statements (on the large compartment B) to further highlight this important information.
4. Revise the ambiguous statement “Break red pin and mix” (found on the smaller compartment A) to read “Break red pin and mix compartment A with compartment B” (or similar language) since it is currently unclear as to what should be mixed together.
5. Please ensure that the barcode and NDC number are presented on the front of the bag label as it appears to have accidentally been omitted from the proposed bag labels.

REPORTING REQUIREMENTS

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

ENCLOSURE:
Container Labeling

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
06/10/2013