DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021703/S-016
NDA 207026/S-001

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Aileen S. Anderson
Regulatory Affairs Specialist
32650 N. Wilson Road
Mail Stop WG2-3S
Round Lake, IL 60073

Dear Ms. Anderson:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 24, 2015 (NDA 207026/S-001), and July 27, 2015 (NDA 21703/S-016), 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) and Phoxillum Renal Replacement Solutions (BK4/2.5 and B22K4/0), respectively.

This "Prior Approval" supplemental new drug application provides for the additional of PrismaSol solutions in polyolefin (non-PVC) presentations to the prescribing information of Phoxillum and PrismaSol solutions in PVC presentations that was approved on January 13, 2015. A Prior Approval Supplement has also been submitted to NDA 021703 for PrismaSol solutions to combine the package inserts for PVC and polyolefin (non-PVC) presentations utilizing the proposed consolidated label for Phoxillum and PrismaSol solutions and the deletion of the trailing zeros from the tables.

APPROVAL & LABELING

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

CONTENT OF LABELING

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 that includes labeling changes 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).

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}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MARY R SOUTHWORTH
12/15/2015