



NDA 021703 S.020  
NDA 207026 S.006

## SUPPLEMENT APPROVAL

Baxter Healthcare Corporation  
Attention: Kelly Jones  
Specialist, Regulatory Affairs  
32650 N. Wilson Road  
Round Lake, IL 60073

Dear Ms. Jones:

Please refer to your Supplemental New Drug Applications (sNDAs) dated August 1, 2018, received August 1, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PrismaSol Renal Replacement Solution BGK0/2.5, BGK4/2.5, BGK2/3.5, BGK2/0, B22GK4/0, BK0/0/1.2, BGK4/0/1.2 and Phoxillum Renal Replacement Solutions BK4/2.5 and B22K4/0.

These “Changes Being Effected” supplemental new drug applications provide for revisions to the prescribing information and container labels for PrismaSol and Phoxillum Renal Replacement Solutions to revise instructions on preparing the solution for administration and to remove one solution (Prismosol BGK 4/3.5).

### **APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is 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 Prescribing Information, 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 include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

### **CARTON AND CONTAINER LABELING**

We acknowledge your August 1, 2018, submission containing final printed carton and container labeling.

### **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  
Division of Cardiovascular and Renal Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

Content of Labeling  
Prescribing Information  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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MARY R SOUTHWORTH  
11/01/2018

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