

NDA 206814/S-007

### SUPPLEMENT APPROVAL

Genus Life Sciences Inc Attention: William Reightler Vice President of Regulatory Affairs 514 North 12th Street Allentown, PA 18102

Dear Mr. Reightler:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 8, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Potassium Chloride Oral Solution, USP, 20 mEq/15 mL and 40 mEq/15 ml.

This "Changes Being Effected" supplemental new drug application provides for change in labeling (container label and PI) to add the language "Protect from Freezing".

# **APPROVAL & LABELING**

We have completed our review of this supplemental application. 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 <a href="http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm">http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm</a>. 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 <a href="http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf">http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf</a>.

The SPL will be accessible via 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 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).

# **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 206814/S-007.**" Approval of this submission by FDA is not required before the labeling is used.

### **PROPRIETARY NAME**

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*, available at <a href="http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf">http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf</a> and "PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012".)

# **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### 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, call Abolade (Bola) Adeolu, Regulatory Business Process Manager, at (301) 796 - 4264.

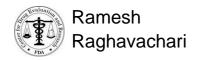
Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD Chief, Branch I Division of Post-Marketing Activities I Office of Lifecycle Drug Products Office of Pharmaceutical Quality Center for Drug Evaluation and Research

**Enclosures:** 

Content of Labeling Carton and Container Labeling



Digitally signed by Ramesh Raghavachari

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