



BLA 761039/S-004

## SUPPLEMENT APPROVAL

Coherus BioSciences, Inc.  
Attention: Olivia Lu  
Associate Director, Regulatory Affairs  
333 Twin Dolphin Drive, Suite 600  
Redwood City, CA 94065

Dear Ms. Lu:

Please refer to your supplemental biologics license application (sBLA), dated and received September 16, 2019, submitted under section 351(k) of the Public Health Service Act for UDENYCA (pegfilgrastim-cbqv) injection.

This Prior Approval supplemental biologics license application provides for revisions to the UDENYCA carton and tray label to prevent product selection errors between Udenyca and Prolia. This submission also includes a Dear HealthCare Provider letter to increase awareness of the issue of packaging confusion until the revised container labels and carton labeling are available for distribution; and a warning sticker for current Udenyca cartons for use in the interim.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the draft carton and container labeling submitted on September 23, 2019, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved BLA 761039/S-004.**” Approval of this submission by FDA is not required before the labeling is used.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Bernetta Lane, Regulatory Health Project Manager, at (301) 796-0937.

Sincerely,

*{See appended electronic signature page}*

Rosanna Setse, MD, PhD  
Deputy Director for Safety (Acting)  
Division of Hematology Products  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

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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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ROSANNA W SETSE  
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