



BLA 125160/S-309

## **SUPPLEMENT APPROVAL**

UCB, Inc  
Attention: Amine Mechalikh, Ph.D.  
Associate Director, Global Regulatory Affairs  
1950 Lake Park Drive  
Building 2100  
Smyrna, GA 30080

Dear Dr. Mechalikh:

Please refer to your supplemental biologics license application (sBLA) dated and received May 10, 2023, and your amendment, submitted under section 351(a) of the Public Health Service Act for Cimzia (certolizumab pegol) injection.

This Prior Approval supplemental biologics license application provides for proposed draft artwork that has been updated to include a linear barcode that contains the National Drug Code (NDC) per 21 CFR 201.25(b).

### **APPROVAL & LABELING**

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

### **CARTON AND CONTAINER LABELS**

We acknowledge your May 10, 2023, submission containing final printed carton and container labeling.

### **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 BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

*{See appended electronic signature page}*

Patrick Lynch, Ph.D.  
Director  
Division of Biotechnology Review and Research I  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

**Enclosure(s):**

Carton and Container Labeling





Patrick  
Lynch

Digitally signed by Patrick Lynch

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