BLA 125160 / S-315

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Marian Saxon, PhD, MS
US Regulatory Science Lead, Cimzia
1950 Lake Park Drive, Building 2100
Smyrna, GA 30080

Dear Dr Saxon:

Please refer to your supplemental biologics license application (sBLA) received March 19, 2025, and your amendments, submitted under section 351(a) of the Public Health Service Act for Cimzia (certolizumab pegol) for injection and Cimzia (certolizumab pegol) injection.

This supplemental application proposes updates to the Prescribing Information in the USE IN SPECIFIC POPULATIONS, *Pregnancy* and CLINICAL PHARMACOLOGY, *Pharmacokinetics* subsections to include pharmacokinetic results from pregnant women who were administered Cimzia during pregnancy and postpartum based on data from Study UP0085 titled, "*A postmarketing, multicenter, longitudinal, prospective, pharmacokinetic, phase 1b study in pregnant women with chronic inflammatory diseases treated with Cimzia (certolizumab pegol).*"

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 enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov,[1] that is identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]
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 BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] 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).

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, contact Jay Fajiculay, PharmD, Senior Regulatory Health Project Manager, at (301) 796-9007 or email at jay.fajiculay@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tara Altepeter, MD
Associate Director for Therapeutic Review
Division of Gastroenterology
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use (revision date 9/2024)

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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.

/s/

TARA A ALTEPETER
09/23/2025 09:31:07 AM