DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125160/S-241

SUPPLEMENT APPROVAL

UCB, Inc.
Attention: Sandra V. Bonsall
Director, Global Regulatory Affairs
1950 Lake Park Drive
Smyrna, GA 30080

Dear Ms. Bonsall:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received November 1, 2013, and your amendments submitted under section 351(a) of the Public Health Service Act for Cimzia (certolizumab pegol).

This "Prior Approval" supplemental biologics application provides for the following:

- Update the Warnings and Precautions (5.2) and Postmarketing Experience (6.2) sections of the Package Insert with information regarding melanoma and Merkel cell carcinoma
- Update the Medication Guide with information about the increased risk for certain skin cancers or hepatosplenic T-cell lymphoma when using TNF blockers
- Update the Prefilled Syringe and Lyophilized Powder Reconstitution Instruction for Use (IFU)

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, 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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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 MS Word format that includes the changes approved in this supplemental application.

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation IIII
Center for Drug Evaluation and Research

ENCLOSURES: Content of Labeling (including Package Insert, Medication Guide, and Instructions for Use)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
04/28/2016