DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125160/174

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

UCB, Inc.
1950 Lake Park Drive
Smyrna, GA 30080

Attention: Sandra Bonsall, RAC
Associate Director, Regulatory Affairs

Dear Ms. Bonsall:

Please refer to your Supplemental Biologics License Application (sBLA), dated October 18, 2011, received December 6, 2011, submitted under section 351 of the Public Health Service Act for Cimzia® (certolizumab pegol).

We acknowledge receipt of your amendments dated January 26 and 31, March 14, and April 9, 2012.

This Prior Approval efficacy supplement to your biologics license application proposes to include information regarding the effect of Cimzia (certolizuma pegol) on vaccines.

This supplement also references the clinical report submission dated March 21, 2011, and the final report dated October 31, 2011, for the following postmarketing requirement listed in the April 11, 2008, approval letter.

6. A placebo-controlled trial designed to assess the effects of Cimzia treatment on antibody responses to a B cell-mediated immunization, using pneumococcal vaccine immunization, and to a T cell-mediated immunization, using influenza vaccine, in patients with active rheumatoid arthritis. The study will measure both antibody titers and rates of clinical response in approximately 100 placebo- and 100 Cimzia-treated patients who will be given polyvalent pneumococcal polysaccharide vaccine and influenza vaccine.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the April 11, 2008, approval that are still open.

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 (text for the package insert, Medication Guide) 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. For administrative purposes, please designate this submission "**Product Correspondence – Final SPL for approved BLA STN 125160/174**"

Also within 14 days, amend all pending supplemental applications 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.

The SPL will be accessible via publicly available labeling repositories.

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 Philantha Bowen, Sr. Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:
Content of Labeling

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

/s/

SALLY M SEYMOUR
04/17/2012