DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125160/92

UCB, Inc.
Attention: Deborah A. Hogerman, Ph.D.
Senior Director, Regulatory Affairs
1950 Lake Park Drive
Smyrna, GA 30080

November 18, 2009

Dear Dr. Hogerman:

Please refer to your supplemental biologic license application dated September 1, 2009 and received September 2, 2009, submitted under section 351 of the Public Health Service Act for Cimzia® (certolizumab pegol).

We acknowledge receipt of your submissions dated October 23, 2009, October 30, 2009, November 2, 2009, November 5, 2009, and November 13, 2009.

Reference is also made to our letter dated August 4, 2009, notifying you, under section 505(o)(4) of the Food, Drug, and Cosmetic Act (FDCA), of the new safety information about the risk of malignancies in pediatric patients, leukemia in adults, and psoriasis-like skin lesions associated with the use of the class of TNF-blockers that we believe should be included in the labeling for Cimzia (certolizumab pegol), and notifying you, under section 505-1 of the FDCA, that based on this new safety information we determined that modifications to your approved risk evaluation and mitigation strategy (REMS) are necessary to ensure that the benefits of the product outweigh the risks.

SAFETY LABELING CHANGES

This supplemental biologic license application provides for revisions to the labeling for Cimzia (certolizumab pegol) consistent with our August 4, 2009, letter and correspondence dated October 16, 2009, October 26, 2009, October 29, 2009, October 30, 2009, November 4, 2009 and November 6, 2009. As part of the labeling, FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208.

We have completed our review of this supplemental application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, including the revised draft Medication Guide you submitted on September 1, 2009, and amended on November 13, 2009.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Cimzia (certolizumab pegol) was originally approved on April 22, 2008, under BLA 125160/0 and modified under BLA 125160/38. An additional modification of the REMS was approved as a single REMS for both BLA 125160 and BLA 125271 on May 13, 2009 as noted in the approval letter. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of the assessments of the REMS.

The proposed modified REMS for Cimzia (certolizumab pegol) includes revisions to the REMS goals and to the Medication Guide to reflect new safety information about malignancies in pediatric patients, leukemia in adults, and psoriasis-like skin lesions associated with use of products within the class of TNF-blockers of which CIMZIA (certolizumab pegol) is a member.

Your modified REMS is approved and appended to this letter. The communication plan, timetable for submission of the assessments of the REMS and your REMS assessment plan will remain the same as that approved on May 13, 2009.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];

- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];

- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

Prominently identify future submissions containing the REMS assessment or proposed REMS modification with the following appropriate wording in bold capital letters at the top of the first page of the submission:

BLA 125160 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125160 REMS ASSESSMENT

PROPOSED REMS MODIFICATION

CONTENT OF LABELING

Within 14 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125160/92." In addition, within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

If you have any questions, call Stacy Barley, Regulatory Project Manager, at (301) 796-2137.

Sincerely,

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

ENCLOSURE: Package Insert
REMS