DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125160/38

UCB, Inc.
Attention: Patricia Fritz, M.S.
Vice President, Global Regulatory Affairs
1950 Lake Park Drive
Smyrna, Georgia, 30080

Dear Ms. Fritz:

Please refer to your supplement to your biologics license application (BLA) dated October 2, 2008, received October 3, 2008, submitted under section 351 of the Public Health Service Act for Cimzia (certolizumab pegol).

This supplemental biologics application provides for a modification to the approved REMS, as requested in our letter dated September 4, 2008.

In accordance with section 505-1 of the Federal Food Drug & Cosmetic Act (FDCA), at the time of approval, we determined that a REMS was necessary for Cimzia, to ensure the benefits of the product outweigh the risks. You submitted your REMS on April 16, 2008, On April 22, 2008, Cimzia (certolizumab pegol) was approved with a REMS. The REMS consisted of a Medication Guide, and a timetable for submission of assessments of the REMS.

On September 4, 2008, we sent a letter invoking our authority under section 505-1(g)(2)(C) of the FDCA, because we determined that your REMS for CIMZIA® must be modified to address new safety information involving the risk of under-recognition of fungal infections including histoplasmosis. On October 2, 2008, you submitted a REMS assessment and a proposed modification of the REMS with a revised Medication Guide and a communication plan, as we requested in our September 4, 2008 letter. On December 19, 2008, you accepted our recommended revisions to the proposed modified REMS that were faxed to you on December 16 and 19, 2008. In addition, you accepted revisions to the proposed modified REMS sent electronically on December 31, 2008.

We have completed our review of this application containing the proposed modified REMS. This application is approved, effective on the date of this letter. The timetable for submission of assessments will remain the same as that approved on April 22, 2008, with the original approval of Cimzia. The timetable you submitted is as follows:

1st FDAAA Assessment:	November 2009
2nd FDAAA Assessment:	May 2011
3rd FDAAA Assessment:	May 2015

Prominently identify future amendments containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

BLA 125160 REMS ASSESSEMENT

NEW SUPPLEMENT FOR BLA 125160
PROPOSED REMS MODIFICATION
< other supplement identification > [if included]
REMS ASSESSMENT [if included]

FDA approved the revised Medication Guide required for distribution with this product in accordance with 21 CFR Part 208 on December 22, 2008.

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

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,

12/31/08.

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: Modified approved REMS