DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN 125160/111

UCB, Inc
1950 Lake Park Drive
Smyrna, GA 30080

Attention: Deborah A. Hogerman, Ph.D.
Senior Director, Regulatory Affairs

Dear Dr. Hogerman:

Please refer to your supplemental biologic license application dated May 20, 2010, and received May 20, 2010, submitted under section 351 of the Public Health Service Act for Cimzia (certolizumab Pegol).

We also refer to your submission dated July 9, 2010.

Reference is also made to our letter dated April 20, 2010, notifying you, under Section 505(o)(4) of the Federal Food, Drug, Cosmetic Act (FDCA) of new safety information that we believe should be included in the labeling for TNF blockers. This information pertains to the risk of peripheral demyelinating disorders, including Guillain-Barre syndrome, demyelinating polyneuropathy, and multifocal motor neuropathy, associated with the use of the class of TNF blockers including Cimzia (certolizumab Pegol)

This supplemental biologic license application provides for revisions to the labeling for Cimzia (certolizumab Pegol) consistent with the agreed upon changes to the language included in our April 20, 2010, Safety Labeling Change Notification Letter and our telephone facsimile dated July 1, 2010.

We have completed our review of this supplemental application. This application is approved, effective on the date of this letter, for use as recommended in the 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 [21 601.14(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 submitted on July 9, 2010). 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 125160/111".**

In addition, within 14 days of the date of this letter, amend any pending supplement for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

The SPL will be accessible via publicly available labeling repositories.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

If you have any questions, call Ladan Jafari, Safety Regulatory Project Manager, at (301) 796-1231.

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(s): Package Insert