UCB, Inc. – 1950 Lake Park Drive – Smyrna, Georgia 30080

16 December 2013

Dr. Donna Griebel, Director
Food and Drug Administration
Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705

BLA 125160
CIMZIA® (certolizumab pegol) - Crohn's Disease
Sequence Number: 0316

With reference to IND 011197
Sequence Number: 1108

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

Dear Dr. Griebel,

Reference is made to IND 11,197 and to the BLA 125160 CIMZIA® (certolizumab pegol) FDA approval letter (22 April 2008) for the treatment of moderately to severely active Crohn's disease in adults. Reference is made to Protocol No. RCPE06J2720 (Study C87035) submitted on 09 September 2008 (Serial No. 686) to fulfill the required PREA postmarketing study established in the 22 April 2008 approval letter. The PREA Postmarketing Requirement (PMR) language from the approval letter is provided below:

> *Conduct a study in pediatric patients, "A Phase II Open-Label Multi-Center Study to Assess the Safety and Efficacy of Certolizumab pegol in Children and Adolescents with Active Crohn's Disease" [Study CDP870-035]. This study is proposed to evaluate the pharmacokinetics, safety and clinical response of pediatric patients, ages 6-17, with moderately to severely active Crohn's disease to treatment with CIMZIA®.*
>
> *Protocol Submission: September 2008*
> *Study Start Date: June 2009*
> *Final Report Submission: October 2013*

Reference is also made to a 17 April 2012 Type C meeting between UCB and FDA to discuss the preliminary findings of the original PREA study (FDA meeting minutes dated 27 April 2012), and FDA written feedback, dated 19 July 2013, regarding a new PREA study (b) (4) proposed by UCB. Finally, reference is made to the FDA's 20 November 2013 PREA Non-Compliance Letter (received 04 December 2013).

UCB is pursuing the fulfillment of this PREA PMR with due diligence and is requesting a deferral extension for the study. The deferral extension request is provided in Module 1.9.2 with this submission.

All of the data and information contained in the attached materials are privileged and confidential as trade secrets and commercial information of UCB, Inc.

Under no condition is the disclosure of any portion of the attached materials to any person or entity other than the Food and Drug Administrations authorized without prior consent of the applicant.

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Should you require additional information, please contact the undersigned at (770) 970 8591 or Leo DiNapoli, Associate Director, Regulatory Affairs at (770) 970-8519 or by email at leo.dinapoli@ucb.com. For technical questions relating to this submission, please contact Monika Wrobel at (770) 970-8399 or by email at monika.wrobel@ucb.com.

Sincerely,

(See appended electronic signature page)

Signed by or on behalf of

Sandra V. Bonsall, RAC
Director, Global Regulatory

Desk Copy: Mr. Matthew Brancazio; Regulatory Project Manager,
DHHS/FDA/CDER/OND/ODE3/DGIEP

CC: CDER Pediatric and Maternal Health Staff

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ELECTRONIC SIGNATURES

Signed by	Meaning of Signature	Server Approval Date (dd-mon-yyyy (HH:mm))
Bonsall Sandra	Regulatory Affairs Approval	16-Dec-2013 17:04 GMT+01

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