

BLA 125160/S-080

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

UCB, Inc.
1950 Lake Park Drive
Building 2100
Smyrna, GA 30080

Attention: Jennifer King
Immunology Regulatory Sciences Lead, Americas

Dear Ms. King:

Please refer to your Supplemental Biologic License Application (sBLA) submitted under section 351 of the Public Health Service Act for Cimzia (certolizumab pegol), which was licensed on May 13, 2009.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 2563-1, which was deferred until December 31, 2016.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a **“DEFERRAL EXTENSION REQUESTED”** in your response. We note that you requested a deferral extension on October 2, 2019; however, we have determined that your request did not qualify for an extension.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a **“RESPONSE TO PREA NON-COMPLIANCE LETTER.”** To facilitate our review, submit this information to your sBLA with a cross-reference letter to the Investigational New Drug Application (IND) to which your protocol has been submitted.

If you have any questions, call Nina Ton, Senior Regulatory Project Manager, at (301) 796-1648.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Director
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

SALLY M SEYMOUR
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