Dear Ms. King:

Please refer to your Supplemental Biologics License Application (sBLA) dated December 14, 2012, received December 17, 2012, and your amendments, submitted under section 351(a) of the Public Health Service Act for Cimzia (certolizumab pegol) Lyophilized Powder and Solution for Subcutaneous Use, 200 mg/mL.

We acknowledge receipt of your amendment dated September 28, 2018, which constituted a complete response to our October 17, 2013, action letter.

This Prior Approval supplemental biologics application proposes a new indication for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

**APPROVAL & LABELING**

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

**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

Reference ID: 4410921
[21 CFR 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 Prescribing Information, and Medication Guide)
and include the labeling changes proposed in any pending “Changes Being Effected” (CBE)
supplements.

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
CM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes
for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA
has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft
Word format that includes the changes approved in this supplemental application, as well as
annual reportable changes. To facilitate review of your submission(s), provide a highlighted or
marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-
up copy should provide appropriate annotations, including supplement number(s) and annual
report date(s).

**CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton and
container labeling, as soon as they are available, but no more than 30 days after they are printed.
Please submit these labeling electronically according to the guidance for industry titled
Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical
Product Applications and Related Submissions Using the eCTD Specifications (April 2018,
Revision 5). For administrative purposes, designate this submission “Final Printed Carton and
Container Labeling for approved BLA 125160/S-237.” Approval of this submission by FDA
is not required before the labeling is used.

**REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new
active ingredients (which includes new salts and new fixed combinations), new indications, new
dosage forms, new dosing regimens, or new routes of administration are required to contain an
assessment of the safety and effectiveness of the product for the claimed indication(s) in
pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are
impossible or highly impracticable as this condition rarely occurs in pediatrics.

Reference ID: 4410921
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 Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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
Acting Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
ENCLOSURES:
   Content of Labeling
   Prescribing Information
   Medication Guide
   Carton and Container Labeling
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/

NIKOLAY P NIKOLOV
03/28/2019 01:14:41 PM
Signed under the authority delegated by Dr. Sally Seymour, Acting Division Director, DPARP.