DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Our STN BLA 125289/25

APPROVAL
July 29, 2010

Centocor Ortho Biotech, Inc.
200 Great Valley Parkway
Malvern, PA 19355

Attention: Salvatore Morello
Associate Director, Global Regulatory Affairs

Dear Mr. Morello:

Please refer to your supplemental biologic license application dated May 19, 2010, and received May 19, 2010, submitted under section 351 of the Public Health Service Act for Simponi (golimumab).

We also acknowledge receipt of your amendment dated July 2, 2010, and your risk evaluation and mitigation strategy (REMS) assessment dated July 2, 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 Simponi (golimumab).

This supplemental biologic license application provides for revisions to the labeling for Simponi (golimumab) 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, and a proposed modification to the approved REMS.

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, text for the Medication Guide

submitted on July 2, 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 125289/25.**

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.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Simponi (golimumab) was originally approved on April 24, 2009, and a REMS modification was approved on November 18, 2009. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of a revision to the Medication Guide.

Your proposed modified REMS, submitted on July 2, 2010, and appended to this letter, is approved.

The timetable for submission of assessments of the REMS will remain the same as that approved on November 18, 2009.

There are no changes to the REMS assessment plan described in our November 18, 2009, letter.

Assessments of an approved REMS must also include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 601.70 and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved

REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

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

BLA 125289
REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125289-PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA 125289
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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,

//Sally Seymour, M.D.//

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure(s): REMS documents, Package Insert, Medication Guide