



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

sBLA 125289/20

**SUPPLEMENT BLA APPROVAL  
RELEASE OF REMS REQUIREMENT**

March 17, 2011

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 Biologics License Application (sBLA), dated February 9, 2010, received February 12, 2010, submitted under section 351 of the Public Health Service Act for Simponi (Golimumab).

We acknowledge receipt of your amendments dated August 30 and October 13, 2010, and January 12 and 18 and February 23, 2011. We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 12, 2011.

This Prior Approval labeling supplement to your biologics license application updates the **WARNINGS AND PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert and the Common Side Effects section of the Medication Guide with new safety information in patients treated with SIMPONI. The supplement also proposes a modification to the approved REMS.

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.

**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 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 package insert, Medication Guide and Patients Instructions for Use) 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 <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 125289/20.**”

Also within 14 days, amend all pending supplemental applications 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 MS Word format that includes the changes approved in this supplemental application.

The SPL will be accessible via publicly available labeling repositories.

We request that the 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 REMS modifications were approved on November 3, 2009, and July 29, 2010. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

As discussed in our email dated March 11, 2011, we have determined that it is no longer necessary for the Medication Guide to be part of the REMS to ensure that the benefits of the drug outweigh its risks. In addition, because the communication plan has been completed and adequately assessed, we have determined that it is no longer necessary to include it in the approved REMS. Therefore, a REMS is no longer required for Simponi (golimumab). We accept the REMS assessment dated January 12, 2011 as the final assessment of this REMS.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR Part 208.

### **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>.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4) to the address above or by fax to 301-847-8444.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this BLA to the following address:

MedWatch Program  
Office of Special Health Issues  
Food and Drug Administration  
10903 New Hampshire Ave  
Building 32, Mail Stop 5353  
Silver Spring, MD 20993

### **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 Miranda Raggio, Regulatory Project Manager, at (301) 796-2109.

Sincerely,

/Sally Seymour /  
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

ENCLOSURES:  
Content of Labeling