



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our STN: BLA 125289/S-33

**SUPPLEMENT BLA APPROVAL**

September 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 Biologics License Application (sBLA), dated September 2, 2010, received September 2, 2010, submitted under section 351 of the Public Health Service Act for Simponi (golimumab).

This Prior Approval labeling supplement to your biologics license application proposes to include information regarding systemic vasculitis to the ADVERSE REACTIONS section of the package insert for Simponi (golimumab).

We have completed our review of this supplemental application. 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 submitted on September 2, 2010), 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/S-33.**"

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.

### **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 Ladan Jafari, Regulatory Project Manager, at (301) 796-1231.

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

ENCLOSURE(S):

Content of Labeling