



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

Our STN: 103772/5278

**APPROVAL**  
July 29, 2010

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

Attention: Barbara Rake  
Director, Global Regulatory Affairs, Immunology

Dear Ms. Rake:

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 Remicade (infliximab).

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 Remicade (infliximab)

This supplemental biologic license application provides for revisions to the labeling for Remicade (infliximab) consistent with our April 20, 2010, Safety Labeling Change Notification letter.

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 submitted on May 19, 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/U>

[CM072392.pdf](#). For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 103772/5278**”.

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.

### **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): Package Insert