DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 103772/5317

August 1, 2011

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT
REMS ASSESSMENT ACKNOWLEDGMENT

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 Biologics License Application (sBLA), dated July 14, 2011, received July 14, 2011, submitted under section 351 of the Public Health Service Act for Remicade (infliximab) Lyophilized Concentrate for IV Injection.

We also acknowledge your assessment of the Remicade (infliximab) risk evaluation and mitigation strategy (REMS) contained in your May 18, 2011, submission.

After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be adequate.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Remicade (infliximab) was originally approved on November 18, 2009, and the most recent REMS modification was approved on February 17, 2011. The REMS consists of a Medication Guide, a Communication plan, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Remicade (infliximab).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Also, the REMS assessment demonstrates that the communication plan has been completed and has met its goals. Therefore, we have determined that it is no longer necessary to include the Medication Guide or the communication plan as elements of the approved REMS to

ensure that the benefits of the drug outweigh the risks. We agree that a REMS for Remicade (infliximab) is no longer required.

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

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