**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STN: sBLA 125289/6

**SUPPLEMENTAL APPROVAL**
November 18, 2009

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

Attention: Bethany K. Paxson
Senior Director, Global Regulatory Liaison

Dear Ms. Paxson:

Please refer to your supplemental biologic license application dated and received September 3, 2009, submitted under section 351 of the Public Health Service Act for SIMPONI (golimumab).

We acknowledge receipt of your submissions dated September 3 and 24, October 1, and November 2 and 3, 2009.

Reference is also made to our letter dated August 4, 2009, notifying you, under section 505(o)(4) of the Food, Drug, and Cosmetic Act (FDCA), of the new safety information about the risk of malignancies in pediatric patients and leukemia in adults associated with the use of the class of TNF-blockers that we believe should be included in the labeling for SIMPONI (golimumab), and notifying you, under section 505-1 of the FDCA, that based on this new safety information, we determined that modifications to your approved risk evaluation and mitigation strategy (REMS) are necessary to ensure that the benefits of the product outweigh the risks.

**SAFETY LABELING CHANGES**

Your supplemental biologic license application provides for revisions to the labeling for SIMPONI (golimumab) consistent with our August 4, 2009, letter, and correspondence dated September 29, October 16, 26, and 29 (2), 2009. As part of the labeling, FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208.

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

**CONTENT OF LABELING**

Within 14 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for package insert, Medication Guide). For administrative purposes, please designate this submission, "**SPL for approved BLA 125289/6**."

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

## RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

This supplemental biologic license application also provides for a proposed modified REMS. The REMS for SIMPONI (golimumab) was approved on April 24, 2009. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission for assessments. The proposed modified REMS for SIMPONI (golimumab) includes revisions to the REMS goals and to the Medication Gide to reflect the goal to communicate and mitigate the risks associated with SIMPONI therapy by educating patients about the serious risks associated with SIMPONI. Your modified REMS, appended to this letter, is approved. The communication plan, timetable for submission of the assessments of the REMS, and your REMS assessment plan will remain the same as that approved on April 24, 2009.

Prominently identify future submissions containing the REMS assessment or proposed REMS modification with the following appropriate wording in bold capital letters at the top of the first page of the submission:

**BLA 125289 REMS ASSESSMENT**

**NEW SUPPLEMENT FOR BLA 125289 REMS ASSESSMENT**

**PROPOSED REMS MODIFICATION**

## LETTER TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this BLA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

Please refer to http://www.fda.gov/cder/biologics/default.htm for information regarding therapeutic biological products, including the addresses for submissions.

This information will be included in your biologics license application file.

If you have any questions, call Sharon Turner-Rinehardt, Regulatory Project Manager, at (301) 796-2254.

Sincerely,

/Larissa Lapteva/

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures (2): Package Insert
REMS