DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: sBLA 103772/5189

JUN 12 2007

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

Attention: Barbara Rake
Associate Director, Worldwide Regulatory Affairs

Dear Ms. Rake:

Your request to supplement your biologics license application for REMICADE® (infliximab) to add new adverse events to the Postmarking Adverse Events section of the label and to update Table 11 of the label, Proportion of patients with elevated ALT in Clinical Trials, for the psoriatic arthritis (PSA) and ankylosing spondylitis (AS) conditions has been approved.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208, which you submitted with this supplement on May 3, 2007.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];
- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for this product [21 CFR 208.24];
- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10-point text; and
- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

Within 21 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. Upon receipt, we will transmit that version to the National Library of Medicine for public

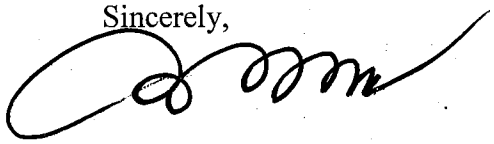
dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 103772/5189." In addition, within 21 days of the date of this letter, amend any pending supplements for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

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

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.

Sincerely,



Bob Rappaport, MD
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