DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

STN: sBLA 103772/5232

December 22, 2008

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

Attention: Barbara Rake
Associate Director, Worldwide Regulatory Affairs

Dear Ms. Rake:

Please refer to your supplemental biologics license application, dated and received October 3, 2008, submitted under section 351 of the Public Health Service Act for REMICADE® (infliximab).

Reference is also made to an FDA letter dated September 4, 2008, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for REMICADE® (infliximab). This information pertains to the risk of histoplasmosis with the use of the class of TNF-inhibitors.

We acknowledge receipt of your communications dated November 24 and December 8, 2008.

Your supplemental biologics license application provides for revisions to the labeling for REMICADE® (infliximab) consistent with our December 5, 2008, communication.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [CFR 601.14(b)].

Your approved Medication Guide should become part of the Risk Evaluation and Mitigation Strategy (REMS) we had requested in our letter of September 4, 2008, for submission by January 2, 2009.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the attached labeling and Medication Guide. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved BLA 103772/5232.**" In addition, within 21 days of the date of

this letter, amend any pending supplement(s) 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 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)].

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please contact Sharon Turner-Rinehardt, Regulatory Health Project Manager, at (301) 796-2254.

Sincerely,

Bob A. Rappaport, MD
Director
Division of Anesthesia, Analgesia,
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert and Medication Guide labeling