

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Rockville, MD 20857



Our STN: BL 103772/5234

Centocor, Inc.  
Attention: Barbara Rake  
Associate Director, Worldwide Regulatory Affairs  
200 Great Valley Parkway  
Malvern, PA 19355-1307

Dear Ms. Rake:

Your request to supplement your biologics license application for REMICADE® (infliximab) to include updated safety language for hepatosplenic T-cell lymphoma (HSTCL) in your label has been approved.

FDA previously approved a Medication Guide required for distribution with this product in accordance with 21 CFR Part 208. FDA hereby approves the revised Medication Guide you submitted on October 10, 2008, as amended by your March 5, 2009 submission.

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)].

As soon as possible, but no later than 14 days from the date of this letter, please 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 and labeling you submitted on March 5, 2009. 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 103772/5234.” In addition, within 14 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 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,

A handwritten signature in blue ink, appearing to read "Joyce Korvick", with a stylized flourish at the end.

Joyce Korvick, M.D., M.P.H.  
Deputy Director for Safety  
Division of Gastroenterology Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

Enclosure: Labeling