DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

APR 05 2005

Our STN: BL 103772/5092

Centocor, Incorporated
Attention: Stella S. Jones, Ph.D.
Vice President, Worldwide Regulatory Affairs
200 Great Valley Parkway
Malvern, PA 19355

Dear Dr. Jones:

Your request to supplement your biologics license application for Infliximab to update the safety information on "Infections" and "Malignancies" in the Warnings and Adverse Reactions sections of the package insert has been approved.

This fulfills your post marketing commitment number one of the December 20, 2000 approval letter for BL 103772/1007 which was as follows:

- To further study the safety and efficacy of infliximab in a randomized, placebo-controlled study of 1000 patients with rheumatoid arthritis who are to be treated initially with either 3mg/kg or 10mg/kg of infliximab in combination with methotrexate. This study will include patients who are treated with multiple disease-modifying anti-rheumatic drugs, and will focus upon the effects of infliximab on the development of infections. Patients initially receiving the lower dose of infliximab will be given higher doses if they do not respond to treatment. The protocol will be submitted for CBER review by January 31, 2001 and finalized by April 30, 2001. The study will be initiated by September 30, 2001 and accrual will be completed by September 30, 2002. A final study report will be submitted by September 30, 2004.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please refer to http://www.fda.gov/cder biologics/default.htm for important information regarding therapeutic biological products, including the address for submissions Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

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

Sincerely,

Marc Walton, M.D., Ph.D.
Director
Division of Therapeutic Biological Internal Medicine Products
Office of Drug Evaluation VI
Center for Drug Evaluation and Research