DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

SEP 29 2004

Our STN: BL 103772/5073

Centocor, Incorporated
Attention: Stella S. Jones, PhD
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 expand the indication to include patients with earlier stage rheumatoid arthritis with moderate to severe disease activity, not previously treated with methotrexate, has been approved.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions. Effective Oct. 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, MD 20852

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

Sincerely,

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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