



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
1401 Rockville Pike  
Rockville MD 20852-1448

Our STN: BL 103772/5004

FEB 27 2002

Stella S. Jones, Ph.D.  
Centocor, Incorporated  
200 Great Valley Parkway  
Malvern, PA 19355-1307

Dear Dr. Jones:

Your request to supplement your biologics license application for Infliximab (Remicade®) to expand the indication to include improving physical function in patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate has been approved.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 2567. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 2567 or Form 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2567 or Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. No comparative promotional claim or claim of superiority over other products should be made unless data to support such claims are submitted to and approved by the Center for Biologics Evaluation and Research.

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

Sincerely yours,

A handwritten signature in black ink that reads "Karen D. Weiss". The signature is written in a cursive style with a large initial 'K' and 'D'.

Karen D. Weiss, M.D.  
Director  
Division of Clinical Trial  
Design and Analysis  
Office of Therapeutics  
Research and Review  
Center for Biologics  
Evaluation and Research

Enclosure:  
Final Draft Labeling