DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

DEC 17 2004

Our STN: BL 103772/5077

Centocor, Inc.
Attention: Stella S. Jones, Ph.D.
Vice President
Worldwide Regulatory Affairs
200 Great Valley Parkway
Malvern PA 19355-1307

Dear Dr. Jones:

Your request to supplement your biologics license application for Infliximab to include a new indication for the treatment of active Ankylosing Spondylitis has been approved.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert. We request that the text of information distributed to patients be printed in a minimum of 10 point font.

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). In addition, you may wish to submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Division of Drug Marketing, Advertising and Communication (HFD-42), Center for Drug Evaluation and Research, 5600 Fishers Lane/Room 8B45, Rockville, MD 20857. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by an FDA Form 2253.

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

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

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

Sincerely,

(b)(6)

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

CONCURRENCE PAGE

Letter Type: LETTER: Approval (AP)

Summary Text: Clinical Supplmt. Efficacy - New/Expanded Indication

S\michaloski\letters\103772/5077ap1
History: michaloski\letters\103772_5077ap1

REVIEW COMPLETION REQUIRED BY: RIS

SS Data Check:

- **Place copy of Approval Ltr. with original signature concurrence page in Archival package behind the "Approval Materials" Tab after LAR (Licensing Action Recommendation).**

RIS Data Check:

- **Verify short summary – Ltr. & Submission screen should match.**
- **Check Letter for PMCs (if PMCs – add "PMCs – Approved With" special characteristic code.)**
- **Check if Major Approval – if so – add code.**
- **Perform Review Completion Process**
- **Milestone: Confirm Approved Status**

cc: HFD-108/A. Pariser
HFD-123/K.Brorson
HFD-123/K. Clouse
HFD-108/J. Siegel
HFD-108/M. Walton
HFD-123/S.Kozlowski
HFD-711/Lee, Kyung Y.
HFD-711/B.Zhen
HFD-109/E.Dye
HFD-109/K. Schneider
HFD-109/C. Michaloski
HFD-106/K. Weiss
HFD-106/G. Jones
HFM-110/RIMS/R. Eastep
HFD-400/M. Dempsey
HFD-46/J.L. Johnson
HFD-006/Exec sec P. Guinn
HFD-013/FOI D.Taub
HFD-013/FOI H. Brubaker
HFD-230/OTCOM/CDER WebMaster
HFD-001/B. Duvall-Miller (if PMC commitments)
HFD-42/DDMAC/M. Kiester

HFD-410/ODS/DSRCS/ Karen Young
HFD-950/OCTAP/T. Crescenzi
HFD-960/OCTAP/G. Carmouze
HFD-040/E. Barrion
HFD-042/C.Gray
HFD-320/DMPQ/ J. Famulare
HFD-322/IPCB/ E. Rivera-Martinez
HFM-555/DMA/ S. Kozlowski
HFD-430/ODS/DDRE (hard copy)
HFD-410/CDER Medwatch Safety Labeling (hard copy)
DRMP BLA file (hard copy)

History: Michaloski\letter\103772_5077ap1

File Name:

Office	Name/Signature	Date
DRMP	(b)(6)	12/16/04
DRMP		12-17-04
DJ DRMP		12/17/04
RRMP		12/17/04
DRMP		12/17/04