

Public Health Service

Food and Drug Administration Rockville, MD 20852

DEC 172004

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 <u>http://www.fda.gov/cder/biologics/default.htm</u> 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.

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

Sincerely,

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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

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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).

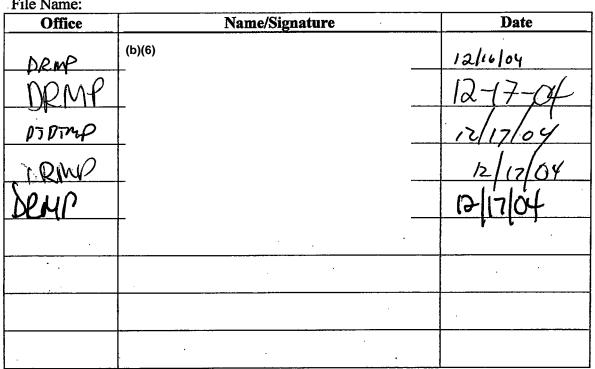
RIS Data Check:

- 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

HFD-108/A. Pariser cc: 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: