DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

DEC 17 2004

Our STN: BL 103772/5090

Centocor, Incorporated
Attention: Stella 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 revise the package insert and patient information sheet with updated information regarding hepatic aminotransferase elevations has been approved.

We acknowledge your plan to disseminate a Dear Health Care Provider letter, informing health care providers of the updated safety information in the Warnings and the Adverse Reactions sections of the package insert by December 21, 2004.

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).

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,

(b)(6)

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

CONCURRENCE PAGE

Letter Type: LETTER: Approval (AP)

Summary Text: Clinical Supplmt. – Labeling Only
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.)**
- **Perform Review Completion Process**
- **Milestone: Confirm Approved Status**

cc: Attached label is sent to everyone
HFD-108/M. Walton
HFD-108/E. Unger
HFD-108/J. Siegel
HFD-108/A. Pariser
HFD-711/K. Lee
HFD-711/B. Zhen
HFD-711/A. Chakravarty
HFD-109/K. Needleman
HFD-109/E. Dye
HFD-106/K. Weiss
HFD-106/G. Jones
HFM-110/RIMS/R. Eastep
HFD-400/ODS M. Dempsey
HFD-006/Exec sec P. Guinn
HFD-013/FOI D.Taub
HFD-013/FOI H. Brubaker
HFD-240/OTCOM/ B. Poole
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 (if pediatric language)
HFD-960/OCTAP/G. Carmouze (if pediatric language)
HFM-570 C. Lee (if clinical PMC commitments)
HFD-328/TFRB Blue File/Mike Smedley
HFD-410/CDER Medwatch Safety Labeling HFD-430/ODS/DDRE (hard copy)
DRMP BLA file (hard copy)

History: K. Needleman: 12.14.04

File Name: S:\Needleman\BLA\Infliximab\103772_5090\BL103772_5090_ap.doc

Office	Name/Signature	Date
DFMP	(b)(6)	12/17/04
DRMP		12/17/04
DRMP		12-17-04
ODBDP		12/17/04
DEMP		12/17/04