DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

Our STN: BL 103795/5225

JUN 28 2005

Amgen, Incorporated
Attention: John S. Walker
Senior Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Mr. Walker:

Your request to supplement your biologics license application for Etanercept to revise the Precautions Drug Interactions section of the package insert to provide information regarding neutropenia in patients treated with both Enbrel and sulfasalazine, to provide a toll-free number for the pregnancy registry and to update the Patient Package Insert (PPI) with information regarding the pregnancy registry has been approved.

We acknowledge you have included in the package insert and the PPI, a toll free phone number regarding the pregnancy registry as referenced in post commitment number 4 of the April 30, 2004, approval for STN # 103795/5149. Post commitment number 4 regarding the full observational study of pregnancy patients is still on-going.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (**http://www.fda.gov/cder/pmc/default.htm**). Please refer to the April 2001 Draft Guidance for Industry: Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see **http://www.fda.gov/cber/gdlns/post040401.htm**) for further information.

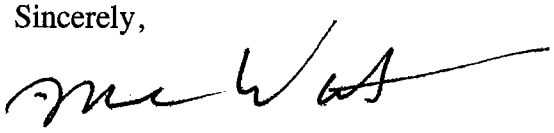
Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

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,



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

Enclosure: Package Insert

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: HFD- 108/R.Neuner
HFD-108/J.Siegel
HFD-108/E. Unger
HFD-108/M. Walton
HFD-109/K.Schneider
HFD-109/E.Dye
HFD-109/C.Michaloski
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
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: Michaloski: 6.9.05: K. Townsend: 6.24.2005

File Name: (S:Michaloski\letters\103795.5225.Labeling.Sulfa.doc)

Division	Name/Signature	Date
DRMP	CM. Chaloski	6-24-05
DRMP	[signature]	6-24-05
DTBOND	[signature]	6/27/05
DRMP	[signature]	7/15/05