



Our STN: BL 125075/31

Genentech, Incorporated  
Attention: Robert L. Garnick, Ph.D.  
Senior Vice President, Regulatory Affairs  
1 DNA Way MS 242  
South San Francisco, 94080-4990

JUN 10 2005

Dear Dr. Garnick:

Your request to supplement your biologics license application for Efalizumab to revise the package insert and the patient package insert to include updated information on serious adverse events, a Warning regarding hemolytic anemia, a Precaution regarding inflammation of the joints (arthritis) and the telephone number for the Pregnancy Registry has been approved.

We acknowledge receipt of your June 10, 2005, letter in which you agreed to issue a Dear Healthcare Provider Letter regarding the new and updated Warnings by July 25, 2005.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

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 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, Maryland 20852

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

Sincerely,

A handwritten signature in black ink, appearing to read 'm WA', with a long horizontal stroke extending to the right.

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/ S. Kress  
HFD-108/L. Marzella  
HFD-108/ M. Walton  
HFD-108/ J. Hyde  
HFD-109/ E. Dye  
HFD-109/ K/ Schneider  
HFD-10-9/ V. Tyson-Medlock  
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-42/DDMAC/M. Kiester  
HFD-410/ODS/DSRCS/ Karen Young  
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:

File Name: s:medlock/125075.31/060805.approval letter

Office	Name/Signature	Date
SRMP	[Signature]	11-10-05
SRMP	[Signature]	1/10/05
SRMP	Kelly [Signature]	2/14/05