DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

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,

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
DRMP	Tyesha Medlock	6-10-05
DTDRMP	[signature]	6/10/05
DRHP	Kelly Lawrence	6/14/05