



Our STN: BL 103795/5191

**MAY 27 2005**

Amgen, Incorporated  
Attention: Douglas Hunt  
Director, Regulatory Affairs  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799

Dear Mr. Hunt:

Your request to supplement your biologics license application for Etanercept to revise the Indications and Usage and the Clinical Studies sections of the package insert based on two year follow-up efficacy, safety, radiographic and physical function data has been approved.

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.

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.

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the addresses 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,

A handwritten signature in black ink, appearing to read 'Marc Walton', with a long horizontal flourish 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

Enclosure: Package Insert