DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

STN: sBLA 103795/5415

SUPPLEMENTAL APPROVAL
November 18, 2009

Amgen, Inc.
One Amgen Center Drive
Mail Stop 17-2-B
Thousand Oaks, CA 91320-1799

Attention: Carol Waldo, MPH, RAC
Director, Regulatory Affairs

Dear Ms. Waldo:

Please refer to your supplemental biologics license application dated September 4, 2009, and received September 8, 2009, submitted under section 351 of the Public Health Service Act for Enbrel (etanercept).

We acknowledge receipt of your submissions dated June 26, September 16 and 25, and October 26, 2009.

Reference is also made to an FDA letter dated August 4, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Enbrel (etanercept). This information pertains to the risk of malignancies in pediatric patients, leukemia in adults, and psoriasis-like lesions associated with use of products within the class of TNF-blockers.

Your supplemental biologics license application provides for revisions to the labeling for Enbrel (etanercept), consistent with our August 4, 2009, letter, and correspondences dated October 9, 16, and 28, and November 5, 2009.

We also refer to the telephone conversation between Kathleen Davies and Carol Waldo on November 18, 2009, where you agreed to revise your class infection language on page 2 of the Medication Guide from, 'an increased chance of getting certain kinds of fungal infections,' back to the original template language of, 'a greater risk for getting certain kinds of fungal infections.'

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Your approved Medication Guide will become part of the proposed Risk Evaluation and Mitigation Strategy (REMS) revisions submitted as pending supplement STN BL103795/ (b) (4).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the attached labeling and Medication Guide. For administrative purposes, please designate this submission, "**SPL for approved BLA 103795/5415**." In addition, within 21 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTER TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this BLA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, please contact Tanya Clayton, Regulatory Health Project Manager, at (301) 796-0871.

Sincerely,

/Larissa Lapteva/

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert
Medication Guide