Our STN BLA 103795/5437   **APPROVAL**
                                                                        July 29, 2010

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

Attention: Marc Kubasak, Ph.D.
                 Senior Manager, Regulatory Affairs

Dear Dr. Kubasak:

Please refer to your supplemental biologic license application dated May 18, 2010, and received
May 18, 2010, submitted under section 351 of the Public Health Service Act for Enbrel
(etanercept).

We also refer to your submission dated July 2, and 13, 2010.

Reference is also made to our letter dated April 20, 2010, notifying you, under Section 505(o)(4)
of the Federal Food, Drug, Cosmetic Act (FDCA) of new safety information that we believe
should be included in the labeling for TNF blockers. This information pertains to the risk of
peripheral demyelinating disorders, including Guillain-Barre syndrome, demyelinating
polyneuropathy, and multifocal motor neuropathy, associated with the use of the class of TNF
blockers including Enbrel (etanercept).

This supplemental biologic license application provides for revisions to the labeling for Enbrel
(etanercept) consistent with the agreed upon changes to the language included in our April 20,
2010, Safety Labeling Change Notification Letter and our telephone facsimile dated July 1,
2010.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA
automated drug registration and listing system (eLIST), the content of labeling [21 601.14(b)] in
structured product labeling (SPL) format, as described at
http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is
identical to the enclosed labeling (text for the package insert submitted on July 13, 2010).
Information on submitting SPL files using eLIST may be found in the guidance for industry

titled "SPL Standard for Content of Labeling Technical Qs and As" at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/U
CM072392.pdf. For administrative purposes, please designate this submission "**Product
Correspondence – Final SPL for approved BLA STN 103795/5437".**

In addition, within 14 days of the date of this letter, amend any pending supplement for this BLA
with content of labeling in SPL format to include the changes approved in this supplement.

The SPL will be accessible via publicly available labeling repositories.

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

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional
labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the
proposed materials in draft or mock-up form with annotated references, and the package insert(s)
to:

> Food and Drug Administration
> Center for Drug Evaluation and Research
> Division of Drug Marketing, Advertising, and Communications
> 5901-B Ammendale Road
> Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the
package insert(s), at the time of initial dissemination or publication, accompanied by a Form
FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For
more information about submission of promotional materials to the Division of Drug Marketing,
Advertising, and Communications (DDMAC), see
http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

If you have any questions, call Ladan Jafari, Safety Regulatory Project Manager, at (301) 796-
1231.

> Sincerely,
>
> *//Sally Seymour, M.D.//*
>
> Sally Seymour, M.D.
> Deputy Director for Safety
> Division of Pulmonary, Allergy, and Rheumatology
> Products
> Office of Drug Evaluation II
> Center for Drug Evaluation and Research

Enclosure(s): Package Insert