DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

STN: BL 103795/5322

Immunex Corporation
40 Technology Way
Mail Stop: ARI TW-7A
West Greenwich, RI 02817

FEB - 1 2007

Attention: Susan Applegate
Sr. Manager, Regulatory Affairs

Dear Ms. Applegate:

Please refer to your supplemental biologics license application dated October 2, 2006, received October 3, 2006, for Enbrel (etanercept).

We acknowledge receipt of your amendments dated, November 22, 2006, December 19, 2006, January 25, and January 29, 2007.

This supplemental biologics license application proposes a new presentation of etanercept drug product: 25 mg of etanercept supplied in a single-dose prefilled syringe (PFS) manufactured at a new manufacturing site, Vetter Pharma-Fertigung GmBH & Co. KG (Vetter), from etanecept drug substance produced at Behring Inglehein Pharma GmbH & Co. KG (BI Pharma) (b)(4) facility.

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.

We remind you of your post-marketing agreements to perform the following, as described in your letter of January 29, 2007. These post-marketing agreements are not subject to the reporting requirements of 21 CFR 601.70.

1. To incorporate "Clear colorless to slightly yellow liquid, may contain some translucent to white amorphous proteinaceous particles" for the 25 mg and 50 mg PFS release and stability specifications. This change will be completed by March 30, 2007.

2. To replace the 25 mg PFS release specification of "Report Results" for the Breakloose/Extrusion assay with a release specification of (b)(4) (b)(4) (Breakloose) and (b)(4) (b)(4) (Extrusion). This change will be completed by March 30, 2007.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and the text for the patient package insert submitted January 25, 2007) and the submitted

labeling (immediate container and carton labels submitted October 2, 2006). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

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

If you have any questions, please contact the Regulatory Project Manager, Pratibha Rana, at (301) 796-1277.

Sincerely yours,

RRoca, MD 2.1.07

Rigoberto Roca, M.D.
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