DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125057/310

SUPPLEMENT APPROVAL

AbbVie Inc.
1 N. Waukegan Road
Bldg AP50; Dept. PA71
North Chicago, IL 60064-6220

Attention: Troy L. ZumBrunnen, Pharm.D.
Director, Regulatory Affairs-PPG

Dear Dr. ZumBrunnen**:**

Please refer to your Supplemental Biologics License Application (sBLA), dated August 10, 2012, received August 13, 2012, submitted under section 351(a) of the Public Health Service Act for Humira™ (adalimumab).

We also acknowledge receipt of your amendments dated October 10, 2012, March 22, and May 8, 2013.

This Prior Approval supplemental biologics application proposes to revise the package insert with new information regarding the risks of tuberculosis, malignancies in pediatric patients and young adults, hypersensitivity reactions, administration of live vaccines to infants exposed to adalimumab *in utero* and during breast feeding, concomitant use of adalimumab and other biologic DMARDs or TNF blockers, and postmarketing reports of pyrexia and Merkel cell carcinoma.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, 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 CFR 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) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Sadaf Nabavian, Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

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):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SALLY M SEYMOUR
05/13/2013