DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125057/S-355

SUPPLEMENT APPROVAL

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

Attention: Tobias Gerwig, Ph.D.
Senior Manager, Regulatory Affairs

Dear Dr. Gerwig**:**

Please refer to your Supplemental Biologics License Application (sBLA), dated August 28, 2013, received August 28, 2013, submitted under section 351(a) of the Public Health Service Act for Humira™ (adalimumab).

We acknowledge receipt of your amendments dated February 4 and 18, 2014.

This "Prior Approval" supplemental biologics application proposes modifications to the Humira Pen 2 Pack Carton introducing a side opening mechanism and a brief injection checklist (Quick Tips) in the inside flap of the carton.

APPROVAL & LABELING

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved BLA 125057/S-355**" Approval of this submission by FDA is not required before the labeling is used.

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

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, Sr. 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:
Carton and Container 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
02/26/2014