DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125057/254

SUPPLEMENT BLA APPROVAL
REMOVE REMS ELEMENT
July 13, 2011

Abbott Laboratories
200 Abbott Park Road
Dept. PA 76, Bldg AP30-1NE
Abbott Park, IL 60064

Attention: Bonnie W. Kain
Associate Director, Regulatory Affairs

Dear Ms. Kain:

Please refer to your Supplemental Biologics License Application (sBLA), dated June 1, 2011, received June 2, 2011, submitted under section 351 of the Public Health Service Act for Humira (adalimumab).

We acknowledge receipt of your amendment dated June 22, 2011 and your and your risk evaluation and mitigation strategy (REMS) assessment dated July 1, 2011.

This Prior Approval labeling supplement to your biologics license application proposes to eliminate the Medication Guide as an element of the approved Humira (adalimumab) REMS.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Humira (adalimumab) was originally approved on April 8, 2010, and the most recent REMS modification was approved on March 14, 2011. The REMS consists of a Medication Guide, communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of eliminating the requirement for the Medication Guide as an element of the REMS.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an

element of the approved REMS to ensure that the benefits of Humira (adalimumab) outweigh the risks.

Therefore, we agree with your proposal, and a Medication Guide is no longer required as part of the REMS for Humira (adalimumab).

Your proposed modified REMS, submitted on June 22, 2011, and appended to this letter, is approved.

The modified REMS consists of communication plan and a timetable for submission of assessments of the REMS.

We remind you that the Medication Guide will continue to be part of the approved labeling for Humira (adalimumab) in accordance with 21 CFR 208.

The timetable for submission of assessments of the REMS will remain the same as that approved on April 8, 2010.

There are no changes to the REMS assessment plan described in our April 8, 2010, letter.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

If you currently distribute or plan to distribute an authorized generic product under this NDA, you must submit a complete proposed REMS that relates only to the authorized generic product. Submit a proposed REMS, REMS supporting document, and any required appended documents as a prior approval supplement. Approval of the proposed REMS is required before you may market your authorized generic product.
Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

BLA 125057 REMS ASSESSMENT

NEW SUPPLEMENT FOR BLA 125057
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR BLA125057
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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 Ladan Jafari, Safety Regulatory Project Manager, at (301) 796-1231.

Sincerely,

/ Sally Seymour /
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):
REMS