DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125057/271

SUPPLEMENT BLA APPROVAL
REMS ASSESSMENT ACKNOWLEDGEMENT
RELEASE REMS REQUIREMENTS
December 13, 2011

Abbott Laboratories
200 Abbott Park Road
Dept. PA76, Bldg AP30-1NE
Abbott Park, IL 60064-6157

Attention: Raymond C. Votzmeyer
Director, Regulatory Affairs

Dear Mr. Votzmeyer:

Please refer to your Supplemental Biologics License Application (sBLA), dated October 7, 2011, received October 7, 2011, submitted under section 351 of the Public Health Service Act for Humira (adalimumab).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated October 7, 2011. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This supplement to your biologics license application proposes to eliminate the requirement for the approved Humira (adalimumab) REMS.

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

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 July 13, 2011. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Humira (adalimumab).

Because the assessment demonstrates that the communication plan has been completed and has met its goals, we have determined that it is no longer necessary to include it as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks.

Therefore, we agree with your proposal, and a REMS for Humira (adalimumab) is no longer required.

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,

/ 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

INSERT ATTACHMENTS/ENCLOSURES