DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

Our STN: BL 125057/108

Abbott Laboratories
Attention: Meg Drew, Immunology Development
Dept RA72, Bldg. AP34-3
200 Abbott Park Rd.
Abbot Park, IL 60064-6188

Dear Ms. Drew,

Your request to supplement your biologics license application for Humira BLA 125057/108 (letter dated March 13, 2007) to revise the Package Insert for three editorial changes in the Clinical Studies Section has been approved. These changes are included in the package insert for BLA 125057/94, approved July 30, 2007, and that version is identical to this one.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

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

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

Sincerely,

MD, MPH 9/5/07

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research