DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: sBLA 125057/94

JUL 30 2007

Abbott Laboratories
Dept. RA76, Bldg. AP30-1 NE
200 Abbott Park Road
Abbott Park, IL 60064-6157

Attention: Ray Votzmeyer
Director, Global Pharmaceutical Regulatory Affairs

Dear Mr. Votzmeyer:

Please refer to your supplemental biologics license application dated September 28, 2006, received September 29, 2006, for HUMIRA (adalimumab).

This supplemental biologics license application, which proposes the addition of statements to the Clinical section of the label regarding the long-term maintenance of efficacy with respect to clinical response, physical function and radiographic response in patients with rheumatoid arthritis, has been approved.

This also fulfills your commitment to submit the final study report within 5 years from the date of approval for Study DE019 as stated in commitment #2 of the December 31, 2002, approval letter.

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

Pursuant to 21 CFR 201.57(c)(18) and 201.80(f)(2), patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BL 125057/94." In addition, within 21 days of the date of this letter, amend any pending supplements for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

We remind you of the waiver of the requirements of 21 CFR 201.57 (d)(8) regarding the length of the Highlights of Prescribing Information section documented in the approval letter dated February 27, 2007. Please note that this waiver applies to the labeling approved for sBLA 125057/94 and all future supplements containing revised labeling, including this supplemental application, unless we notify you otherwise.

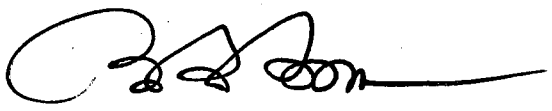
You may submit draft copies of the proposed introductory advertising and promotional labeling with a cover letter requesting advisory comments to the Food and Drug Administration, Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communication, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Final printed advertising and promotional labeling should be submitted at the time of initial dissemination, accompanied by a FDA Form 2253.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

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,



Bob Rappaport, MD
Director
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Rheumatology Products
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