



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

STN: BL 125057/60

February 16, 2007

Abbott Laboratories
2D-RA76/AP30-1NE
200 Abbott Road Park
Abbott Park, IL 60064-6157

Attention: James D. Steck, Director
Global Pharmaceutical Regulatory Affairs

Dear Mr. Steck:

Please refer to your supplemental biologics license application dated July 21, 2005. The Agency received all fees owed and your supplemental biologics license application for Humira[®] (adalimumab) was accepted as of April 19, 2006.

We also acknowledge receipt of your submissions dated June 9 and July 28, 2006, and February 7 and 8, 2007.

This supplemental biologics license application proposes changes to the PRECAUTIONS section of the package insert to add language regarding the impact of adalimumab on pneumococcal and influenza vaccine immunizations in rheumatoid arthritis patients.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

This fulfills Post-Marketing Commitment #1 as stated in the letter dated December 31, 2003 for STN 125057/11.

To conduct a study to determine the impact of adalimumab on pneumococcal vaccine and influenza vaccine immunization in rheumatoid arthritis patients. The study will be initiated by October 15, 2003, accrual will be completed by February 28, 2005, the study will be completed by April 30, 2005, and the final study report will be submitted by July 31, 2005.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and the text for the patient package insert). 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(f)(2), patient labeling must be reprinted at the end of the package insert.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] 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 for the package insert and patient package insert. For administrative purposes, designate this submission "**Content of Labeling for approved BLA 125057/60.**" Upon receipt and verification that the content of labeling in SPL format is identical to the approved labeling text, we will transmit that version to the National Library of Medicine for public dissemination.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirements for these indications.

You may wish to 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.

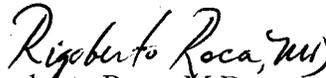
All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence to support that claim.

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

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

If you have any questions, call Paul Z. Balcer, Regulatory Project Manager at (301) 796 1173.

Sincerely,



Rigoberto Roca, M.D.
Deputy Division Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure