



BLA 125057/S-367

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT**

AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064

Attention: Dawn Territo
Associate Director, Regulatory Affairs

Dear Ms. Territo:

Please refer to your Supplemental Biologics License Application (sBLA), dated December 6, 2013, received December 6, 2013, submitted under section 351(a) of the Public Health Service Act for Humira[®] (adalimumab).

We acknowledge receipt of your amendments dated February 25, May 23, June 4, and September 16, and 26, 2014.

This Prior Approval supplemental biologics application provides for the treatment of Polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 to less than 4 years of age.

APPROVAL & LABELING

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

This submission also contains the final report for the following postmarketing commitment listed in the February 21, 2008, approval letter for BLA 125057/S-114.

2. Conduct a compassionate use study in patients 2 to 4 years of age with moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) to collect pharmacokinetic data in 6 to 20 patients and to collect safety data in 30 patients according to the safety assessment specified in postmarketing commitment number 1. The proposed protocol will be submitted for the Division's review by March 31, 2008. The final protocol will be submitted by May 30, 2008. The study will be initiated by August 31, 2008. A 5-year interim report will be submitted by June 30, 2014. The final study report will be submitted by December 31, 2021.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that postmarketing commitment #1 listed in the February 21, 2008, approval letter is still open.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the Package Insert, text for the Instructions for Use, Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this BLA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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, Sr. Regulatory Project Manager, at (301) 796-2777.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SARAH K YIM
09/30/2014
Signing for Badrul Chowdhury, M.D., Ph.D.