



BLA 125433/2

SUPPLEMENT APPROVAL

Janssen Biotech, Inc.
Welsh & McKean Roads
P.O. Box 776
Spring House, PA 19477

Attention: Salvatore Morello
Director, Global Regulatory Affairs

Dear Mr. Morello:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received September 18, 2013, submitted under section 351(a) of the Public Health Service Act for Simponi Aria (golimumab, for intravenous use), 50 mg/4 mL vial.

This "Changes Being Effected" supplemental biologics application provides for correction of the weekly maintenance methotrexate dose in the Clinical Trials Section (14) from (15-25 mg/kg) to (15-25 mg).

APPROVAL & LABELING

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 enclosed, agreed-upon labeling text.

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 none of these criteria apply to your application, you are exempt from this requirement.

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 Christine Chung, R.Ph., Regulatory Project Manager, at (301) 796-3420.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director of Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

SALLY M SEYMOUR
02/04/2014