DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125433/S-017

SUPPLEMENT APPROVAL

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

Attention: Paul Imm, PharmD
Associate Director, Global Regulatory Affairs

Dear Dr. Imm:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received on February 8, 2016, submitted under section 351(a) of the Public Health Service Act for Simponi Aria (golimumab) Injection, 50 mg/4 mL.

We also refer to our approval letter dated February 22, 2016, which contained the following error:

> In the Recent Major Changes section of the prescribing information, the date for "Warnings and Precautions (5/11) was listed as 3/2016. This was corrected to reflect the correct date, **2/2016**.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain February 22, 2016, the date of the original approval letter.

This Changes Being Effected supplemental biologics application proposes to add information regarding post-marketing reports of infusion related reactions to Section 5.11 Hypersensitivity Reactions and to Section 6.2 Postmarketing Experience of the prescribing information for Simponi Aria.

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.

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 and text for the 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 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 Carol F. Hill, Senior Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Sally Seymour, MD
Deputy Director for 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
02/22/2016