



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125289/53

SUPPLEMENT BLA APPROVAL

September 7, 2011

Janssen Biotech, Inc.
200 Great Valley Parkway
Malvern, PA 19355

Attention: Salvatore Morello
Associate Director, Global Regulatory Affairs, Immunology

Dear Mr. Morello:

Please refer to your Supplemental Biologics License Application (sBLA), dated July 7, 2011, received July 7, 2011, submitted under section 351 of the Public Health Service Act for Simponi (golimumab).

We acknowledge receipt of your amendments dated August 12, and 26, and September 2, 2011.

We also refer to our letter dated June 7, 2011, notifying you, under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA), of new safety information that we believe should be included in the labeling for Simponi (golimumab). This information pertains to the risk of serious infection including Legionella and Listeria in patients treated with Simponi (golimumab).

This supplemental new drug application provides for revisions to the labeling for Simponi (golimumab) consistent with our June 7, 2011, Safety Labeling Change Notification letter and telephone facsimiles dated August 1, and 23, 2011.

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.

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 include the labeling changes proposed in any pending "Changes Being Effectuated" (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>. For administrative purposes, please designate this submission “**Product Correspondence – Final SPL for approved BLA STN 125289/53**”

Also within 14 days, amend all pending supplemental applications 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.

The SPL will be accessible via publicly available labeling repositories.

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
Division of Drug Marketing, Advertising, and Communications
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. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4) to the address above or by fax to 301-847-8444.

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 Ladan Jafari, Safety Regulatory Project Manager, at (301) 796-1231.

Sincerely,

/ Sally Seymour /

Sally Seymour, M.D.

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

INSERT ATTACHMENTS/ENCLOSURES