



BLA 125370/47

**SUPPLEMENT APPROVAL**

Human Genome Sciences, Inc.  
14200 Shady Grove Road  
Rockville, MD 20850

Attention: Wendy Valinski, Director  
Global Regulatory Affairs

Dear Ms. Valinski:

Please refer to your Supplemental Biologics License Application (sBLA), dated June 13, 2013, received June 13, 2013, submitted under section 351(a) of the Public Health Service Act for Benlysta (belimumab).

We acknowledge receipt of your amendments dated October 25 and December 11, 2013.

This Prior Approval supplemental biologics application provides for changes to: Package Insert-WARNINGS AND PRECAUTIONS in Section 5. 4 - *Hypersensitivity Reactions, Including Anaphylaxis*, the PATIENT COUNSELING INFORMATION in Section 17.1 - *Advice for the Patient*, and the Medication Guide in order to update labeling regarding hypersensitivity reactions. In addition, this supplement provides for the removal of the reference to a Pregnancy Registry in the Highlights section and proposes revised language regarding latex in the HOW SUPPLIED/STORAGE AND HANDLING Section of the product label.

**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.

**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, Medication Guide) 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>.

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 Philantha Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

*{See appended electronic signature page}*

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

ENCLOSURE(S):  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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SALLY M SEYMOUR  
12/13/2013