DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125370/53

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 January 10, 2014, received January 10, 2014, submitted under section 351(a) of the Public Health Service Act for Benlysta (belimumab).

We acknowledge receipt of your amendments dated January 22, 27, and 30, March 21, and April 2, 2014.

This Prior Approval supplemental biologics application provides for revisions to the package insert to update the WARNINGS AND PRECAUTIONS subsection 5. 2 - *Warnings and Precautions, Serious Infections* and the PATIENT COUNSELING INFORMATION subsection 17.1 - *Advice for the Patient*, and Medication Guide in order to provide information regarding the risk of Progressive Multifocal Leukoencephalopathy (PML) in patients with Systemic Lupus Erythematosus (SLE).

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 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.

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.

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.

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 Philantha Bowen, Senior Regulatory Project Management Officer, 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:
Content of Labeling

These are not all the possible side effects of BENLYSTA. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of BENLYSTA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BENLYSTA for a condition for which it was not prescribed.

This Medication Guide summarizes the most important information about BENLYSTA. For more information about BENLYSTA, talk with your healthcare provider.

You can ask your healthcare provider or pharmacist for information about BENLYSTA that is written for healthcare professionals.

For more information about BENLYSTA, go to www.BENLYSTA.com or call 1-877-423-6597.

What are the ingredients in BENLYSTA?

Active ingredient: belimumab.
Inactive ingredients: citric acid, polysorbate 80, sodium citrate, sucrose.

Manufactured by
Human Genome Sciences, Inc.
Rockville, Maryland 20850
US License No. 1820

Marketed by

GlaxoSmithKline
Research Triangle Park, NC 27709

This Medication Guide has been approved by the U.S. Food and Drug Administration.

April 2014

BNL:XMG

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
04/03/2014