DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125370/S-064
BLA 761043/S-007

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Human Genome Sciences, Inc.
1250 South Collegeville Road
Collegeville, PA 19426

Attention: Wendy Valinski, MS
Director, Global Regulatory Affairs

Dear Ms. Valinski:

Please refer to your Supplemental Biologics License Applications (sBLAs) and associated amendments, for Benlysta (belimumab) Lyophilized Powder for Intravenous Injection, 120 mg and 400 mg dated October 26, 2018, and for Benlysta (belimumab) Solution for Subcutaneous Injection, 200 mg/1 mL dated April 17, 2019, submitted under section 351(a) of the Public Health Service Act.

Prior Approval supplemental biologics application 125370/S-064 provides for expansion of the approved indication for the treatment of patients with active, antibody systemic lupus erythematosus (SLE) to include children aged 5 to 17 years of age.

Prior Approval supplemental biologics application 761043/S-007 provides for alignment of the common prescribing information for the two routes of administration of Benlysta.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 Prescribing Information, Medication Guide,

Instructions for Use) 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 include 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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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.

We note our approval letter dated March 9, 2011, waiving the pediatric study requirements for ages 0 to 4 years 11 months because necessary studies are impossible or highly impracticable. This is because too few children have the disease condition to study.

With this submission, we note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application (BLA 125370).

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submission dated July 17, 2018, containing the final report for the following postmarketing requirement listed in the postapproval new postmarketing requirement letter for BLA 125370 dated November 14, 2016.

2661-15 Phase 2, multicenter study to evaluate the safety, efficacy, and pharmacokinetics of belimumab plus background standard therapy in 70 pediatric subjects ages 5 years to 17 years of age with active systemic lupus erythematosus (SLE)

We have reviewed your submission and conclude that the above requirement was fulfilled.

This completes your postmarketing requirement acknowledged in our November 14, 2016, letter.

We remind you that there are postmarketing requirements and postmarketing commitments listed in the March 9, 2011, approval letter that are still open.

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 Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, 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.

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
Acting Director
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Prescribing Information
Medication Guide
Instructions for Use

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NIKOLAY P NIKOLOV
04/26/2019 01:15:11 PM
Signed under the authority delegated by Dr. Sally Seymour, Acting Division Director, DPARP.