CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761043Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	July 19, 2017
Application Type and Number:	BLA 761043
Product Name and Strength:	Benlysta (belimumab) Injection 200 mg/mL single-dose autoinjector 200 mg/mL single-dose prefilled syringe
Product Type:	Single ingredient, combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Human Genome Sciences, Inc./GSK
Panorama #:	2017- 16242547
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD
DMEPA Team Leader:	Sarah K. Vee, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Benlysta, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Benlysta (belimumab) for injection for intravenous use, was initially approved under BLA 125370 on March 9, 2011 for intravenous administration in single-use vials. The proprietary name, Benlysta, was found acceptable by DMEPA in OSE Memorandum #2010-2551 dated February 25, 2011[a]. On September 26, 2016, the Applicant submitted the name Benlysta (b) (4) *** for review under BLA 761043 for a new dosage form, injection for subcutaneous use, in an autoinjector and pre-filled syringe presentation of belimumab intended for subcutaneous administration. However, following a November 29, 2016 teleconference with DMEPA, the Applicant submitted an amendment to the proprietary name submission on December 2, 2016 for the proposed the proprietary name Benlysta (b) (4), which was found acceptable in OSE Review #2016-10390901 dated December 21, 2016[b]. On July 7, 2017, the Applicant submitted the name, Benlysta, (b) (4) for the proposed subcutaneous presentations.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 7, 2017 proprietary name submission.

- Intended Pronunciation: ben LIST ah
- Active Ingredient: belimumab
- Indication of Use: treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
- Route of Administration: Subcutaneous
- Dosage Form: injection
- Strength: 200 mg/mL
- Dose and Frequency: 200 mg administered subcutaneously once weekly

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[a] The proprietary name, Benlysta, was found acceptable by DMEPA in following:

Holmes, L. Proprietary Name Review for Benlysta IND 9970. Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2009 MAR 26. RCM No.: 2008-1164.

Mena-Grillasca, C. Proprietary Name Review for Benlysta BLA 125370. Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2010 AUG 13. RCM No.: 2010-1311.

Mena-Grillasca, C. Proprietary Name Review for Benlysta 125370 Memorandum. Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2011 FEB 25. RCM No.: 2010-2551.

[b] Patel, M. Proprietary Name Review for Benlysta BLA 761043. Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2016 DEC 21. RCM No.: 2016-10390901.

- How Supplied: 200 mg in a 1-mL single-dose autoinjector with 27-gauge, half-inch needle attached, 200 mg in a 1-mL single-dose prefilled glass syringe with 27-gauge, half-inch needle attached
- Storage: refrigerated between 2°C to 8°C (36°F to 46°F) and protected from light. Keep the product in the original carton to protect from light until the time of use. Do not freeze.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[c].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Benlysta, is the FDA approved proprietary name of the intravenous formulation of belimumab. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error. We discuss the use of a single proprietary name for multiple dosage forms in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 12, 2017 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 1 (see Appendix A1 for a description of FAERS database) for name confusion errors involving ***Benlysta*** that would be relevant for this review.

[c] USAN stem search conducted on July 5, 2017.

Table 1. FAERS Search Strategy	
Search Date	July 11, 2017
Drug Name	*BENLYSTA* [product name] BENLYSTA;BELIMUMAB (BENLYSTA) 800 MG GLAXO SMITHKLINE PHARMACEUTICALS;BELIMUMAB – BENLYSTA- 400 MG HUMAN GENOME SCI/GSK;BENLYSTA;BENLYSTA;BENLYSTA 71136;BENLYSTA (BELIMUMAB);BENLYSTA (BELIMUMAB) 120MG/VIAL GLAXOSMITHKLINE;BENLYSTA (BELIMUMAB) 400MG/VIAL GLAXOSMITHKLINE;BENLYSTA (BENLYSTA);BENLYSTA 120 MG;BENLYSTA 120 MG GSK;BENLYSTA 120 MG VIAL GSK;BENLYSTA 120 MG/VIAL HUMAN GENOME SCIENCE;BENLYSTA 120 ML;BENLYSTA 120MG;BENLYSTA 120MG GLAXO SMITH KLINE;BENLYSTA 120MG GLAXOSMITHKLINE;BENLYSTA 120MG HUMAN GENOME SCIENCES + GSK;BENLYSTA 120MG HUMAN GENOME SCIENCES, INC;BENLYSTA 120MG VIAL GLAXO SMITH KLINE;BENLYSTA 120MG, 400MG HUMAN GENOME SCIENCES INC;BENLYSTA 120MG/VIAL GLAXO SMITH KLINE;BENLYSTA 200 GLAXOSMITHKLINE;BENLYSTA 400 AND 120 MG VIALS;BENLYSTA 400 MG;BENLYSTA 400 MG AND 120 MG HUMAN GENOME SCIENCES;BENLYSTA 400 MG GLAXO SMITH;BENLYSTA 400 MG GLAXO SMITH KLINE;BENLYSTA 400 MG GSK;BENLYSTA 400 MG VIAL GSK;BENLYSTA 400 MG/VIAL HUMAN GENOME SCIENCE;BENLYSTA 400 ML;BENLYSTA 400MG 120MG (GSK);BENLYSTA 400MG GLAXO SMITH KLINE;BENLYSTA 400MG HUMAN GENOME SCIENCES, INC;BENLYSTA 400MG VIAL GSK;BENLYSTA 400MGX2;BENLYSTA 477 MG;BENLYSTA 500MG GSK;BENLYSTA 520 MG GLAXO SMITH;BENLYSTA 520 MG GSK;BENLYSTA 520MG GLAXO SMITH;BENLYSTA 600 MG;BENLYSTA 600 MG - VARIES ON WEIGHT GLAXOSMITHKLINE/HUMAN GENOME SCIENCES ; 592 MG 10 MG/KG 8/30/11 E;BENLYSTA 700 MG MONTHLY IV;BENLYSTA 750 MG, 1 IN 28 D, INTRAVENOUS DRIP;BENLYSTA BENLYSTA;BENLYSTA FOR INJECTION GSK;BENLYSTA GSK;BENLYSTA HGS;BENLYSTA HGS/GSK;BENLYSTA INFUSION

Table 1. FAERS Search Strategy	
	(BELIMUMAB);BENLYSTA NOT PROVIDED HGS/GSK;BENLYSTA POWDER FOR INFUSION;BENLYSTA POWDER FOR SOLUTION FOR INFUSION;BENLYSTA SOLUTION FOR INJECTION;BENLYSTA UNKNOWN HGS/GSK;BENLYSTA UNKNOWN HS/GSK;BENLYSTA(BELIMUMAB) 800 MG GLAXO SMITH KLINE;BENLYSTA(BENLIMUMAB);BENLYSTA, 120 MG, VIAL HUMAN GENOME SCIENCES INC.;BENLYSTA, 520 MG;BENLYSTA, GLAXOSMITHKLINE;BENLYSTA, HGS/GSK;BENLYSTA, UNKNOWN, HUMAN GENOME SCIENCES, INC.;CLARITIN/BENLYSTA;BELIMUMAB;BELIMUMAB (BELIMUMAB);BELIMUMAB (POWDER FOR INFUSION);BELIMUMAB 460MG;BELIMUMAB POWDER FOR INFUSION;BELIMUMAB SOLUTION FOR INJECTION;BLINDED BELIMUMAB;LYMPHOSTAT-B (BELIMUMAB) [product verbatim]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED

Table 1. FAERS Search Strategy	
	WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	October 1, 2016 – July 1, 2017

A FAERS search was conducted in a previous review from the time the intravenous formulation of Benlysta was approved to October 1, 2016, which yielded 0 relevant cases.[d] The current FAERS search as outlined above yielded no cases of name confusion with the proprietary name Benlysta. Therefore, the use of the name, Benlysta, remains viable at this time.

2.2.5 Multiple Dosage Forms under a Single Proprietary Name

The currently marketed product, Benlysta, is currently approved as a single-dose vial for intravenous injection, and has been marketed since 2011. The applicant now proposes a new subcutaneous injection dosage form of belimimab, in an autoinjector and pre-filled syringe presentation under the same proprietary name, Benlysta. We note that there are some differences between the two formulations (e.g. strength, dose, frequency, route of administration, dosage form). Differences between the proposed formulation and the current marketed formulation are listed in Table 2 below.

Table 2. Comparison of the Proposed Product With the Marketed Product		
	Benlysta (proposed)	**Benlysta (marketed)**
Approval Date	n/a	March 9, 2011
Active Ingredient	belimumab	belimumab
Indication of Use	Treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) who are receiving standard therapy	Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy
Route of Administration	Subcutaneous	Intravenous
Strength	200 mg/mL	120 mg/1.5 mL (80 mg/mL) 400 mg/4.8 mL (80 mg/mL)
Dosage Form	Injection	Lyophilized powder for injection
Dose and Frequency	200 mg subcutaneously once weekly	10 mg/kg infused intravenously over 1 hour at 2-week intervals for the first 3 doses and at 4-

[d] Patel, M. Proprietary Name Review for Benlysta BLA 761043. Silver Spring (MD): FDA, CDER, OSE, DMEPA, (US); 2016 DEC 21. RCM No.: 2016-10390901.

		week intervals thereafter
How Supplied	200 mg in a 1-mL single-dose autoinjector with 27-gauge, half-inch needle attached 200 mg in a 1-mL single-dose prefilled glass syringe with 27-gauge, half-inch needle attached	120 mg in a 5-mL single-use vial 400 mg in a 20-mL single-use vial
Preparation/Administration	Recommended that the first injections should be under the supervision of a healthcare professional. After a healthcare provider determines it is appropriate, a patient may self-inject or a caregiver may administer.	Reconstituted and diluted by a healthcare professional
Likely Care Environment for Dispensing and Use	Home (i.e., self administration/ self injection in an outpatient setting)	Medical setting (i.e., physician's office, clinic, or hospital)

We consulted the Division of Pulmonary, Allergy, and Respiratory Products (DPARP) to determine the clinical consequences of confusion between the two formulations. The clinical team noted that there are no significant safety concerns if the subcutaneous dose was inadvertently administered by the intravenous route of administration using either formulation. Additionally, per the clinical reviewer, an intravenous dose is unlikely to be inadvertently administered by the subcutaneous route of administration because the volume needed to achieve the dose would exceed the allowable volume for subcutaneous administration.

It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Moreover, we have not identified any medication errors with the proprietary name, Benlysta. In addition, the residual risk of confusion between the intravenous and subcutaneous formulations of the product may be mitigated through labels and labeling interventions. Therefore, we find the Applicant's proposal to market the proposed subcutaneous formulation with the proprietary name Benlysta acceptable.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Michael Sinks, OSE project manager, at 240-402-2684.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Benlysta, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your July 7, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

[e] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
   - Highly similar pair: combined match percentage score ≥70%.
   - Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
   - Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

[f] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg

Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of

Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

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07/19/2017

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07/19/2017

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	December 21, 2016
Application Type and Number:	BLA 761043
Product Name and Strength:	Benlysta (b) (4) (belimumab) injection 200 mg/mL
Total Product Strength:	200 mg/mL
Product Type:	Single ingredient, combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Human Genome Sciences, Inc./GSK
Panorama #:	2016-10390901
DMEPA Primary Reviewer:	Madhuri R. Patel, PharmD.
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD., MPH
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