CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761201Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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)

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Date of This Review:	January 15, 2021
Responsible OND Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	BLA 761201
Product Name and Strength:	Semglee (insulin glargine-yfgn) injection 100 units/mL (U-100)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	Mylan Pharmaceuticals Inc. (Mylan)
OSE RCM #:	2020-2570
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761201.

1.1 Regulatory History

Mylan was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

insulin glargine-yfgn

FDA generated a four-letter suffix, -yfgn. This suffix was evaluated using the principles described in the applicable guidance[b].

We determined that the FDA-generated suffix -yfgn, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated January 13, 2021, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) via e-mail on January 15, 2021.

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[a] Harris, D. General Advice Letter for BLA 761201. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2020 Oct 26.
[b] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find the suffix -yfgn acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to insulin glargine-yfgn. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendation for Mylan Pharmaceuticals Inc.

We find the nonproprietary name, insulin glargine-yfgn, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, insulin glargine-yfgn will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

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/

CARLOS M MENA-GRILLASCA
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DANIELLE M HARRIS
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PROPRIETARY NAME MEMORANDUM

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)

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Date of This Review:	October 21, 2020
Application Type and Number:	BLA 761201
Product Name and Strength:	Semglee (insulin glargine-xxxx)[a] injection, 100 units/mL
Total Product Strength:	1,000 units per 10 mL vial 300 units per 3 mL pen
Product Type:	Single Ingredient Product, Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Mylan GmbH (Mylan)
Panorama #:	2020-41763992
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDCES
DMEPA Team Leader:	Idalia E. Rychlik, PharmD
DMEPA Associate Director of Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

[a] Since the proper name for Semglee has not yet been determined, "insulin glargine-xxxx" is used as the nonproprietary name for this product.

1 INTRODUCTION

This memorandum evaluates the proposed proprietary name, Semglee, from a safety perspective. On July 29, 2020, Mylan submitted a request to BLA 761201 under section 351(k) of the Public Health Service Act, to review the proposed proprietary name for its proposed interchangeable biosimilar to US-Lantus (BLA 021081).

1.1 REGULATORY HISTORY

On June 11, 2020, Mylan's marketing application for an insulin glargine product was approved with the proprietary name Semglee, under NDA 210605 (upon approval on June 11, 2020, the marketing application ceased to exist as an NDA and was deemed to be an approved BLA under section 351(a) of the PHS Act). According to Mylan's July 29, 2020 proprietary name submission, they are seeking the same indications, dosage forms, and routes of administration as US-licensed Lantus. Thus, Mylan proposes to use the same proprietary name for its approved insulin glargine product and its proposed interchangeable biosimilar to US-licensed Lantus (BLA 210605 and BLA 761201, respectively), as they maintain that this naming strategy would reduce the risk of medication errors due to possible confusion between these products.[b]

Upon further review, we identified preliminary concerns regarding Mylan's proposed naming strategy and conducted a teleconference with Mylan, Division of Diabetes, Lipid Disorders, and Obesity (DDLO), Office of Therapeutic Biologics and Biosimilars (OTBB), Office of Regulatory Policy (ORP), and Office of Biotechnology Products (OBP) on September 22, 2020. Primary among our concerns was the risk for confusion among healthcare providers and lay users if the Semglee product licensed under section 351(a) and the proposed interchangeable biosimilar to Lantus submitted under section 351(k) used the same proprietary name. In response to the concerns discussed during the teleconference, Mylan stated that they plan to transition away from marketing their Semglee product licensed under 351(a) (BLA 210605) if the interchangeable biosimilar product is approved.[c]

On October 13, 2020, Mylan submitted their product transition plan and timeline for their Semglee product licensed under section 351(a) and the proposed interchangeable biosimilar to US-licensed Lantus submitted under section 351(k). Specifically, they propose to "*introduce the 351(k) product into commercial distribution as soon as possible upon the receipt of licensure and in parallel exhaust the existing 351(a) labelled product within the supply chain.* (b) (4)

[b] Request for Proprietary Name Review for MYL-1501D insulin glargine (BLA 761201). Morgantown (WV): Mylan Pharmaceuticals Inc; 2020 Jul 29. Available from: \\CDSESUB1\evsprod\bla761201\0001\m1\us\118-proprietary-names\request-for-proprietary-name-review.pdf.

[c] Thomas, T. General Advice Letter: Teleconference Meeting Minutes for Semglee (insulin glargine-xxxx). Silver Spring (MD): FDA, CDER, OSE (US); 2020 Oct 15. BLA 761201.

(b) (4)[d] Thus, we determined that Mylan's proposal addresses our concerns and that use of the name Semglee for their proposed biosimilar interchangeable 351(k) product may be acceptable.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Semglee would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Semglee.

2.2 SAFETY ASSESSMENT

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

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) via email on October 15, 2020. At that time, we also requested additional information or concerns that could inform our review. Per email correspondence from the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on October 21, 2020, they stated no additional concerns with the proposed proprietary name, Semglee.

3 CONCLUSION

Based on our safety evaluation, we determined that the proposed proprietary name, Semglee, is acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO MYLAN GMBH

We have completed our review of the proposed proprietary name, Semglee, and have concluded that this name is acceptable for BLA 761201.

If any of the proposed product characteristics as stated in your submission, received on July 29, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[d] SEMGLEE 351(a) to 351(k) Product Transition Plan (BLA 761201). Morgantown (WV): Mylan Pharmaceuticals Inc; 2020 Oct 13. Available from: \\CDSESUB1\evsprod\bla761201\0007\m1\us\111-information-amendment\multidisciplinary-information-amendment-response-to-informat.pdf.

[e] USAN stem search conducted on October 15, 2020.

4 REFERENCE

1. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

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/s/

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10/21/2020 09:57:02 AM

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