CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208673Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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

Date of This Review:	September 27, 2016
Application Type and Number:	NDA 208673
Product Name and Strength:	Soliqua 100/33 (insulin glargine and lixisenatide), injection, 100 units insulin glargine and 33 mcg lixisenatide per mL
Total Product Strength:	300 units insulin glargine and 99 mcg lixisenatide per 3 mL pen
Product Type:	Multi-Ingredient and Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sanofi-Aventis
Panorama #:	2016-10150379
DMEPA Primary Reviewer:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader (Acting):	Hina Mehta, PharmD
DMEPA Deputy Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

This review evaluates the proprietary name Soliqua 100/33, submitted by Sanofi on September 6, 2016, based on the Agency's recommendation to include the numerical modifier "100/33" in the proprietary name[a]. In addition, based on the recommendation from the Division of Metabolism and Endocrinology Products (DMEP), Sanofi revised the submission to include one pen device instead of the two pens that were originally proposed. Therefore, the proprietary name submitted for this review is for the pen device containing 100 units of insulin glargine and 33 mcg of lixisenatide per mL.

2 REGULATORY HISTORY

Sanofi submitted the proprietary names Soliqua (b) (4) and Soliqua (b) (4) on January 8, 2016 and January 20, 2016 under NDA 208673. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed names unacceptable from a safety perspective due to the use of the modifiers (b) (4)

On June 16, 2016, Sanofi submitted an amendment to request review of the following modifier options for the two pen devices proposed under the pending NDA: (1) Soliqua and (b) (4) *** and (2) Soliqua and (b) (4) ***. However, the Division of Metabolism and Endocrinology Products (DMEP) and DMEPA had residual concerns that the risk for medication errors with this product would be adequately mitigated through the use of a modifier if two pen devices were available.

On August 11, 2016, Sanofi submitted an amendment to the pending NDA modifying the labeling submission to include one pen device instead of the two pens that were originally proposed following a teleconference between the Agency and Sanofi representatives on August 8, 2016.[c]

On September 2, 2016, the Agency recommended that the applicant include the numerical modifier "100/33" in the proprietary name.[d]

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[a] Sanofi-Aventis. Cover letter-11 August-2016-NDA Amendment-Response to FDA request dated 08-Aug-2016-Labeling (insulin glargine, lixisenatide NDA 208673). Bridgewater (NJ): Sanofi-Aventis. 2016 Aug 11.

[b] Conrad A. Proprietary Name Review for Soliqua (b) (4) and Soliqua (b) (4) (NDA 208673). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 March 31. Panorama # 2016-2740671, 2016-2740673, 2016-2706472.

[c] Sanofi-Aventis. Cover letter-11 August-2016-NDA Amendment-Response to FDA request dated 08-Aug-2016-Labeling (insulin glargine, lixisenatide NDA 208673). Bridgewater (NJ): Sanofi-Aventis. 2016 Aug 11.

[d] White M. COR-NDAIR-01 (Information Request) for Soliqua (NDA 208673). . Silver Spring (MD): FDA, CDER, OND, DMEP (US); 2016 Sept 6. NDA 208673.

3 METHODS AND DISCUSSION

3.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product via their September 21, 2016 email. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

3.2 SAFETY ASSESSMENT

We found the root name Soliqua conditionally acceptable in our previous review but the modifiers [redacted] (b) (4) were found to be unacceptable.

For the reassessment of the proposed proprietary name, we searched the USAN stem list to determine if the name contains any USAN stems as of the last update. There is no USAN stem present in the proprietary name.[e]

Soliqua is a multi-ingredient product containing 100 units of insulin glargine and 33 mcg of lixisenatide per mL; thus, the addition of the numerical modifiers to the proprietary name was recommended by the Agency to help convey to health care practitioners the presence of two ingredients in the formulation. This nomenclature is similar to what is currently used in marketed insulin/insulin mixtures, where the numerical modifier conveys the percentage of each insulin in the mixture. We find the proposed proprietary name, Soliqua 100/33, acceptable.

4 CONCLUSIONS

The proposed proprietary name, Soliqua 100/33, is acceptable.

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

4.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Soliqua 100/33, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your September 6, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[e] USAN stem search conducted September 12, 2016.

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.

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/s/

ARIANE O CONRAD
09/27/2016

HINA S MEHTA
09/28/2016

LUBNA A MERCHANT
09/28/2016

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Date of This Review:	March 31, 2016
Application Type and Number:	NDA 208673
Product Name and Strength:	Soliqua [redacted] (b) (4) (insulin glargine and lixisenatide) injection, 100 units and 50 mcg per mL Soliqua [redacted] (b) (4) (insulin glargine and lixisenatide) injection, 100 units and 33 mcg per mL
Total Product Strength:	300 units insulin glargine and 150 mcg lixisenatide per 3 mL pen 300 units insulin glargine and 99 mcg lixisenatide per 3 mL pen
Product Type:	Multi-ingredient and Combination Product
Rx or OTC:	RX
Applicant/Sponsor Name:	Sanofi-Aventis
Panorama #:	2016-2740671, 2016-2740673, 2016-2706472
DMEPA Primary Reviewer:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Deputy Director:	Lubna Merchant, M.S., PharmD
DMEPA Director:	Todd Bridges, RPh

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/s/

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03/31/2016

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