CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209637Orig1s000

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:	February 17, 2017
Application Type and Number:	NDA 209637
Product Name and Strength:	Ozempic (semaglutide) injection, 1.34 mg/mL
Total Product Strength:	2 mg/1.5 mL
Product Type:	Single ingredient combination product (drug + device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novo Nordisk
Panorama #:	2016-11762660
DMEPA Primary Reviewer:	Susan Rimmel, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Ozempic, 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 submitted an external name study, conducted by (b) (4), for this product. We note that the external study provided in the current submission is the same study provided in the Applicant's June 29, 2015, proprietary name submission for IND 79754 (OSE RCM # 2015-826232).

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Ozempic, on June 29, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Ozempic, acceptable on October 9, 2015.[a]

1.2 PRODUCT INFORMATION

The following product information is provided in the December 6, 2016, proprietary name submission.

- Intended Pronunciation: oh-ZEM-pick
- Active Ingredient: semaglutide
- Indication of Use: an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 2 mg/1.5 mL (1.34 mg/mL)
- Dose and Frequency: 0.25 mg once weekly for four weeks, then 0.5 mg once weekly for four weeks, then increase if needed to 1 mg once weekly
- How Supplied: three variants of a prefilled pen device each containing 2 mg/1.5 mL
    - Sample pack (1 pen) – delivers 0.25 mg, 0.5 mg (b) (4)
    - One pack (1 pen) – delivers 0.25 mg, 0.5 mg (b) (4)
    - Two pack (2 pens) – delivers 1 mg only
- Storage: When not in use, store at 2°C to 8°C (35.6°F to 46.4°F), not frozen and protected from light. When in use, store below 30°C (86°F), not (b) (4) frozen and protected from light.

[a] Vee, S. Proprietary Name Review for Ozempic IND 79754. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2015 Oct 09. RCM No.: 2015-826232.

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 Metabolism and Endocrinology Products (DMEP) 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.[b]

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Ozempic, in their submission. 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.

2.2.3 FDA Name Simulation Studies

Ninety-eight practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 23, 2016, e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[b] USAN stem search conducted on December 12, 2016.

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