CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213051Orig1s000

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:	May 8, 2019
Application Type and Number:	IND 114464, NDA 213051, NDA 213182
Product Name and Strength:	Rybelsus (semaglutide) tablet, 3 mg, 7 mg, and 14 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novo Nordisk Inc. (Novo)
Panorama #:	2018-27266112, 2019-30202491, 2019-30252981
DMEPA Safety Evaluator:	Ariane O. Conrad, PharmD, BCACP, CDE
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Rybelsus, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Novo submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submissions received on November 13, 2018 under IND 114464 and on March 20, 2019 under NDA 213051 and NDA 213182:

- Intended Pronunciation: rye bel' sus
- Active Ingredient: semaglutide
- Indication of Use:
  - an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (NDA 213051)
  - to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular (b) (4) disease (NDA 213182)
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 3 mg, 7 mg, and 14 mg
- Dose and Frequency: The usual dosage for this product is 3 mg, 7 mg or 14 mg once daily. The maximum daily dose is 14 mg.
- How Supplied: 30-day supply (3x10) of 3 mg, 7 mg, or 14 mg blister pack (Trade Packs); also 30-day supply (3x10) of 3 mg in blister pack (Sample Pack)
- Storage: Do not store above 30°C (86°F). Do not freeze. (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Rybelsus would not misbrand the proposed product per their November 27, 2018 email. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Rybelsus.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Rybelsus.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Novo indicated in their submission that the proposed proprietary name, Rybelsus, is a "blank canvas". This proprietary name is comprised of a root name, Rybelsus, 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE November 27, 2018 email, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to Rybelsus at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Thirty-eight practitioners participated in DMEPA's prescription studies for Rybelsus. The responses did not overlap with any currently marketed products. However, one voice study participant interpreted the name as 'Rivelsus', which sounds like the currently marketed product Rivelsa. Orthographically, the prefixes of the name pair ('Ryb' *versus* 'Riv') look different. Phonetically, the last syllables ('sus' *versus* 'sa') sound different. Rivelsa is an oral contraceptive, available as a dose pack containing varying strengths of levonorgestrel-ethinyl estradiol and ethinyl estradiol (0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg ethinyl estradiol). Rybelsus will be available as 3 mg, 7 mg, or 14 mg tablets. We note that the product strength would have to be specified on a prescription or medication order for Rybelsus and the product strengths of Rybelsus and Rivelsa do not overlap. See Appendix E for our evaluation of this name pair.

Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 39 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

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[a] USAN stem search conducted on January 18, 2019.

[b] POCA search conducted on January 18, 2019 in version 4.3.

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