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APPLICATION NUMBER:

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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:	March 22, 2017
Application Type and Number:	NDA 209803
Product Name and Strength:	Steglatro (ertugliflozin) tablets, 5 mg and 15 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck Sharp & Dohme Corp.
Panorama #:	2017-12352707
DMEPA Primary Reviewer:	Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Steglatro, 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

The Applicant previously submitted the proposed proprietary name, Steglatro on January 6, 2016. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Steglatro, acceptable on April 6, 2016 under OSE# 2016-2484877.[a]

1.2 PRODUCT INFORMATION

The following product information is provided in the January 4, 2017 proprietary name submission:

- Intended Pronunciation: steh-GLA-troh
- Active Ingredient: ertugliflozin
- Indication of Use: Treatment of patients with Type 2 diabetes mellitus
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 5 mg, 15 mg
- Dose and Frequency: Recommended starting dose is 5 mg once daily in the morning with or without food. In patients tolerating 5 mg who require additional glycemic control, the dose may be increased to 15 mg once daily.
- How Supplied:

Tablet Strength	Tablet Count	Package
5 mg and 15 mg	7 (7 days), 30 (30 days), 90 (90 days)	75 cc HDPE (b) (4)
5 mg	500 (bulk)	120 cc HDPE (b) (4)
15 mg	500 (bulk)	10 oz HDPE (b) (4)
5 mg and 15 mg	HUD Unit Dose: unit dose foil/foil blisters (b) (4) (b) (4).	Foil/foil blister

- Storage: Store at USP Controlled Room Temperature (15°C-25°C). Protect from moisture.

[a] Conrad, A. Proprietary Name Review for Steglatro IND 106447. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 April 06. RCM No.: 2016-2484877.

- Container and Closure Systems: The intended trade package configuration consists of high-density polyethylene (HDPE) bottles [redacted] (b) (4) for potential total product counts of weekly, 30-day and 90-day supply and pharmacy re-dispensing bottles of 500s [redacted] (b) (4). The intended sample package configuration will be a weekly HDPE bottle. The intended hospital unit dose (HUD) package is unit dose foil/foil blisters [redacted] (b) (4).

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, Steglatro 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 (90) 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, January 24, 2017 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 in their January 26, 2017 email.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

[b] USAN stem search conducted on January 27, 2017.

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