

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208223Orig1s000

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)

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Date of This Review:	November 6, 2015
Application Type and Number:	NDA 208223
Product Name and Strength:	Zembrace SymTouch (sumatriptan) Injection 3 mg/ 0.5 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Dr. Reddy's Laboratories
Panorama #:	2015-1595257
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Zembrace SymTouch, 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

Dr. Reddy's Laboratories previously submitted the proposed proprietary name, Zembrace (b) (4) on April 8, 2015. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Zembrace (b) (4) acceptable in OSE Review (b) (4) and (b) (4), dated July 1, 2015.

Subsequently, on September 29, 2015, Dr. Reddy's Laboratories withdrew the conditionally approved proprietary name Zembrace (b) (4) and requested review of proposed proprietary name, Zembrace SymTouch. The root name is the same but the device related modifier was changed from (b) (4) to 'SymTouch', i.e. Zembrace SymTouch.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 29, 2015 proprietary name submission.

- Intended Pronunciation: Zem-brace Sim-Touch
- Active Ingredient: sumatriptan succinate
- Indication of Use: acute treatment of migraine with or without aura in adults
- Route of Administration: subcutaneous injection
- Dosage Form: injection
- Strength: 3 mg/0.5 mL
- Dose and Frequency: 3 mg at onset of migraine; may repeat if needed ≥ 1 hour after initial dose. (b) (4)
- How Supplied: Prefilled, single-use, disposable injection device, box of 4 autoinjectors.
- Storage: Controlled room temperature of 15°C - 30° C (59°F - 86°F)
- Container and Closure Systems: Single use, prefilled injection device, 1 mL clear, USP Type I glass syringe closed with (b) (4) closure

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 Neurology Products (DNP) concurred with the findings of OPDP's misbranding 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 name¹.

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Zembrace SymTouch, in their submission. This proprietary name is comprised of two words, a root name 'Zembrace' and a modifier 'SymTouch'. The root name and the modifier do not contain any components (i.e., route of administration, numbers, etc.) that are misleading or can contribute to medication errors.

The root name, Zembrace, was reviewed and conditionally approved in a previous review² and is not further evaluated in this review. Our evaluation of the modifier is discussed in Section 2.2.5.

2.2.3 *FDA Name Simulation Studies*

Seventy 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, October 8, 2015 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

¹USAN stem search conducted on October 28, 2015.

² Harris, J. Proprietary Name Review for Zembrace (b) (4) (IND 118668 and NDA 208223). 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); 2015 Jul 1. 25 p. OSE RCM No.: (b) (4)

2.2.5 FMEA of Modifier SymTouch

The Applicant proposes to use the modifier ‘SymTouch’ for this product and indicated that the modifier, ‘SymTouch,’ represents the device that is used with the medication but has no intended meaning. They did not provide data to support that the proposed modifier is understood by health care practitioners and patients; however, the naming convention to use a modifier to represent a specific device has been used before (e.g. Imitrex STATdose and Novolog FlexPen). The SymTouch device is not available on its own and we do not anticipate that the modifier ‘SymTouch’ will be written on its own without the root name.

We note that the modifier “SymTouch” is similar to the modifier “FlexTouch” which is a modifier used for the products Levemir and Novolog. In our prescription simulation verbal study one participant misinterpreted the modifier as ‘FemTouch’, however, it is unclear if this misinterpretation was due to association with the modifier ‘FlexTouch’ or due to phonetic similarity of the beginning syllables (‘Sym-‘ vs. ‘Fem’). Although the names share the same ending word ‘Touch’ in the modifiers, the root names have sufficient orthographic and phonetic differences to prevent name confusion.

We note that modifiers may sometimes be omitted. If the modifier SymTouch is omitted, there is no other Zembrace product currently marketed from which Zembrace SymTouch will need to be distinguished. Additionally, we did not identify any names that can be confused with ‘SymTouch’ during our review of the ISMP’s List of Products with Drug Name Suffixes³. Therefore, we do not find the modifier, SymTouch, misleading or vulnerable to confusion and find it acceptable for this product.

2.2.6 Communication of DMEPA’s Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 5, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on November 6, 2015, they stated no additional concerns with the proposed proprietary name, Zembrace SymTouch.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-496-0097.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Zembrace SymTouch, and have concluded that this name is acceptable.

³ Institute for Safe Medication Practices. ISMP’s List of Products with Drug Name Suffixes. 2010.

If any of the proposed product characteristics as stated in your September 29, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 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.

2. *ISMP's List of Products with Drug Name Suffixes*

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. ⁴

⁴ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there medical and/or coined abbreviations in the proprietary name?
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals

(pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders, which are recorded electronically.

- c. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Zembrace SymTouch Study (Conducted on October 13, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Zembrace SymTouch SQ injection stat; may repeat in 1 hr prn</i></p>	<p>Zembrace SymTouch</p> <p>Inject subcutaneously x 1 as needed. May repeat in one hour as needed.</p>
<p><u>Outpatient Prescription:</u></p> <p><i>Zembrace SymTouch Inject SC x 1 prn. May repeat in one hr. prn Disp #4</i></p>	<p>Disp #4</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
78 People Responded

Study Name: Zembrace SymTouch

Total	27	24	27	
SIMBRACE SEEM TOUCH	0	1	0	1
SIMBRACE SIMTOUCH	0	3	0	3
SYMBRASE SYMTOUCH	0	1	0	1
ZEMBRACE SEPFOUCH INJECT SC	1	0	0	1
ZEMBRACE SIMTOUCH SQ	0	1	0	1
ZEMBRACE SYM TOUCH	2	0	2	4
ZEMBRACE SYMFAUCT	1	0	0	1
ZEMBRACE SYMLAUCH	1	0	0	1
ZEMBRACE SYMLOUCH	1	0	0	1
ZEMBRACE SYMTORCH	0	0	1	1
ZEMBRACE SYMTOUCH	17	1	21	39
ZEMBRACE SYMTOUCH SQ INJECTION	0	0	1	1
ZEMBRACE SYMTOVET	1	0	0	1
ZEMBRACE SYMTOUCH	1	0	0	1
ZEMBRANCE SYMTOUCH	0	0	1	1
ZEMBRAZE SYMTOUCH	1	0	0	1
ZEMBRICE SYMTOUCH	1	0	0	1
ZEMBVACC SYMTOUCH	0	0	1	1
ZIMBRACE FEMTOUCH	0	1	0	1
ZIMBRACE SIMTOUCH	0	9	0	9
ZIMBRACE SYMTOUCH	0	1	0	1
ZIMBRACE ZIMTOUCH	0	1	0	1
ZIMBRAISE SIMTOUCH	0	1	0	1
ZIMBRASE SIMTOUCH	0	1	0	1
ZYMBRACE SIMTOUCH	0	2	0	2
ZYMBRACE SYMTOUCH	0	1	0	1

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/s/

JUSTINE HARRIS
11/09/2015

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Date of This Review: July 1, 2015
Application Type and Number: IND 118668 and NDA 208223
Product Name and Strength: Zembrace (b) (4) (sumatriptan succinate) injection
3 mg/0.5 mL
Product Type: Drug-Device Combination Product
Rx or OTC: Rx
Applicant/Sponsor Name: Dr. Reddy's Laboratories
Panorama #: (b) (4)
DMEPA Primary Reviewer: Justine Harris, RPh
DMEPA Team Leader: Danielle Harris, PharmD, BCPS

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