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RESEARCH**

APPLICATION NUMBER:

208684Orig1s000

208685Orig1s000

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:	July 28, 2016
Application Type and Number:	NDA 208684 and 208685
Product Name and Strength:	Emflaza (deflazacort) Tablets 6 mg, 18 mg, 30 mg, and 36 mg Oral suspension 22.75 mg/mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Marathon Pharmaceuticals, LLC
Panorama #:	2016-8884510 and 2016-8884305
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Emflaza***, which was found conditionally acceptable under IND 19258 on September 18, 2015.¹ We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, we searched the USAN stem list ² to determine if the name contains any USAN stems as of the last USAN updates. We also searched the Electronic Drug Registration and Listing System (eDRLS) database ³ to identify any names with potential orthographic, spelling, and phonetic similarities with Emflaza that were not identified in our previous review, and found to have an overlap in strength with Emflaza. See Sections 2.2 and 2.3 for results of these searches.

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 Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 United States Adopted Names (USAN) Search

DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. Our search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Emflaza will be available in strengths of 6 mg, 18 mg, 30 mg, 36 mg, and 22.75 mg/mL. Since 18 mg, 22.75 mg/mL and 36 mg are not commonly marketed strengths, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Emflaza that were not identified in our previous POCA search, and found to have an overlap in strength with Emflaza.

¹ Myers, D. Proprietary Name Review for Emflaza IND 119258. 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 SEPT 18 Panorama No 2015-992898.

² USAN stem search conducted on July 11, 2016

³ eDRLS search conducted on July 12, 2016

We reviewed the names retrieved from the eDRLS database, and found one name with the same beginning letter ‘E’ and determined the name to be of low similarity to the proposed name Emflaza. This is supported by the FDA’s Phonetic and Orthographic Computer Analysis (POCA) system which calculates a combined POCA score of 32% for this name pair. We did not find any other names with potential orthographic, spelling, and phonetic similarities with Emflaza. See Appendix I for a complete listing.

Table 1A. eDRLS Search Results	POCA score
Estradiol	32

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Corwin Howard, OSE project manager, at 240.402.8654.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 29, 2016 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. Electronic Drug Registration and Listing System (eDRLS) database

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

3. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences

No.	Name
1.	Adidas
2.	Balmers Hanryeoncho SuSeungHwa
3.	BEEVENOM SLEEPING MASK
4.	Cedax
5.	CLARINSMEN Antiperspirant ALL DAY DRY ALCOHOL-FREE
6.	Cleocin Phosphate
7.	Clindamycin in 5 Percent Dextrose
8.	Clinical Strength Miracle Dry Antiperspirant Deodorant
9.	Coconut Tuberose
10.	Concerta
11.	Cytomegalovirus Remedy

No.	Name
12.	Deep Cleaning Astringent
13.	Deepest Deep
14.	Gillette Sport Undefeated Invisible
15.	Halls Sugar Free Extra
16.	Hibiscus Breeze
17.	JAMU Sexty
18.	JEJUN RADIANCE FOAM CLEANSER
19.	Letomint
20.	Manzatin-EDiaper Rash Skin Protectant
21.	Methylphenidate Hydrochloride
22.	Minitran
23.	Mojito Sun
24.	NOXAFIL
25.	Old Spice
26.	Passion Fruit Kiss
27.	Pineapple Paradise
28.	REVITEALIZE
29.	REVITEALIZE
30.	Scott-Vincent Borba
31.	Secret Invisible
32.	SOLV X
33.	Spathery
34.	Spiriva
35.	Strattera
36.	Strensiq
37.	Suntegrity Lip CPR Lipstick
38.	THE FIRST WHITENING SLEEPING MASK
39.	Thicker Fuller Hair - Dandruff Sulfate Free
40.	Wilde Orchid

No.	Name
41.	Xtampza
42.	Zorvolex

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/s/

JUSTINE HARRIS
07/28/2016

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08/01/2016