CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761089Orig1s000

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)

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Date of This Review:	January 4, 2018
Application Type and Number:	BLA 761089
Product Name and Strength:	Ajovy (fremanezumab) injection, 150 mg/mL
Total Product Strength:	225 mg/1.5 mL
Product Type:	Single-Ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Teva Branded Pharmaceutical Products R&D, Inc.
Panorama #:	2017-18365737
DMEPA Safety Evaluator:	Ebony Whaley, PharmD, BCPPS
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ajovy, which was found conditionally acceptable under IND 106533 on September 20, 2017.[a]

We note that there is a change in dosing and delivery device for BLA 761089. All other product characteristics remain the same (see Table 1).

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA concurred with the findings of OPDP's assessment of the proposed name. The Division of Neurology Products (DNP) provided further comments pertaining to the name (see Section 2.3).

2.2 SAFETY ASSESSMENT

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. We also evaluated previously identified names taking into account the change in dosing and delivery device (see Table 1). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

DMEPA also conducted a gap analysis and searched the POCA database to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review # 2017-15055305. Our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Table 1. Comparison of dosing and delivery device of IND 106533 and BLA 761089

	IND 106533	BLA 761089
Dosing	(b) (4)	Two subcutaneous dosage options of Ajovy are available: o 225 mg monthly or 675 mg every 3 months (quarterly) (b) (4)

[a] Whaley, E. Proprietary Name Review for Ajovy IND 106533. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 SEP 20. Panorama No. 2017-15055305.

		(b) (4)
Delivery device	○ 225 mg/1.5 mL (b) (4)	○ 225 mg/1.5mL pre-filled syringe

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The October 23, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

In response to the OSE, November 13, 2017 e-mail, DNP expressed concerns regarding the potential for the proposed proprietary name Ajovy*** to be confused with another proposed proprietary name Aimovig***. DNP noted that both products are within the same pharmacological category (anti-calcitonin gene-related peptide [CGRP] receptor antibody). We evaluated this name pair in our previous review and found there are sufficient orthographic and phonetic differences. Specifically, the infix of Ajovy ('-jo-') contains a downstroke letter and the infix of Aimovig*** ('-mo-') contains a bump letter. Additionally, the first ('Ah-' vs. 'Aim-'), second ('-joe-' vs. '-oh-'), and third ('-vee' vs. '- vig') syllables of the name pair sound different. The lack of similarity between this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) which calculates a combined orthographic and phonetic score of 49% for this name pair.[b] This score suggests low similarity between the names. Thus, we continue to maintain our finding that there is minimal risk of name confusion for this name pair.

2.4 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on December 13, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DNP on January 4, 2018, they stated no additional concerns with the proposed proprietary name, Ajovy.

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 Ruth Maduro, OSE project manager, at 240-402-4232.

[b] POCA search conducted on January 4, 2018 in version 4.1.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 16, 2017 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.

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/s/

EBONY A WHALEY
01/04/2018

LOLITA G WHITE
01/04/2018