CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208277Orig1s000

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:	November 4, 2015
Application Type and Number:	NDA 208277
Product Name and Strength:	Fycompa (perampanel) Oral Suspension, 0.5 mg/mL
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eisai Inc.
Panorama #:	2015-5593579
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Fycompa, 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 proposed proprietary name, Fycompa, was found acceptable in OSE Review 2012-1636, dated August 13, 2012 for the oral tablet formulation. Fycompa oral tablets 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg (NDA 202834) were approved on October 22, 2012.

The applicant submitted the name, Fycompa, for the oral suspension formulation under review for NDA 208277 on September 9, 2015.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 9, 2015 proprietary name submission.

- Intended Pronunciation: fi-COM-puh
- Active Ingredient: perampanel
- Indication of Use: adjunctive therapy for the treatment of:
    - Partial-Onset Seizures with or without secondarily generalized seizures in patients with epilepsy 12 years of age and older
    - Preliminary Generalized Tonic-Clonic Seizures in patients with epilepsy 12 years of age and older
- Route of Administration: oral
- Dosage Form: suspension
- Strength: 0.5 mg/mL
- Dose and Frequency:

    Dosing in the absence of enzyme-inducing antiepileptic drugs (AEDs)

    - Starting dose: 2 mg once daily at bedtime
    - May increase dose based on clinical response and tolerability by increments of 2 mg once daily no more frequently than at weekly intervals
    - Recommended maintenance dose: Partial-Onset Seizures – 8 to 12 mg once daily at bedtime; Primary Generalized Tonic-Clonic Seizures – 8 mg once daily at bedtime

    Dosing in the presence of AEDS

- Starting dose: 4 mg once daily at bedtime. Increase at increments of 2 mg no more frequently than at weekly intervals to a max of 12 mg

- How Supplied: (b) (4) packaged with a dispenser set that provides two 20-ml graduated oral dosing syringes and a push-in bottle adapter.
- Storage: Do not store above 30°C (86°F). Do not freeze. Use within 90 days after the first opening of the bottle.
- Container and Closure Systems: child-resistant closure
- DEA Schedule: C III

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 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[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed proprietary name for the perampanel oral suspension formulation, Fycompa, is the approved proprietary name for the perampanel tablet formulation, and is not derived from any other existing name or meaning. 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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 25, 2015, 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.

[1]USAN stem search conducted on September 25, 2015.

2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Fycompa that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	September 17, 2015
Drug Name	Fycompa [product name]
Event (MedDRA Terms)	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)
Date Limits	October 22, 2012 (approval date for Fycompa) to September 17, 2015 (FDA Rcvd Dates)

Following exclusions, the search yielded zero relevant cases.

2.2.5 Multiple Dosage Forms under a Single Proprietary Name

Fycompa is currently marketed under NDA 202834 as an oral tablet in multiple strengths; 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg. We considered the appropriateness of using the proprietary name, Fycompa, for the oral suspension proposed under NDA 208277, which would represent a brand name extension for this product line. We note that the Fycompa oral tablets and the proposed oral suspension share the same active ingredient (perampanel) and the same indication; for use (partial onset seizures with or without generalized seizures and primary generalized tonic-clonic seizures) and same patient population (patients with epilepsy 12 years of age and older). The proposed dosing regimen and titration are the same for both dosage forms with no dosing differences noted in the proposed Prescribing Information. The products differ in some characteristics including strength (0.5 mg/mL vs. 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, and 12 mg) and dosage form (oral suspension vs. tablets). It is common and accepted practice to have a product line with multiple dosage forms share one proprietary name and, while we note the strengths and dosage forms are different, these differences can be managed via labeling. Given that the products share the same active ingredient, indications for use, patient population and dosing regimen we believe that use of the name, Fycompa, for this proposed product is acceptable.

Additionally, the applicant asserts that the proposed Fycompa oral suspension and the currently marketed tablets are bioequivalent; however, this matter is still under review. Provided that the review team confirms that these products are bioequivalent and have no clinically significant differences, we do not anticipate this brand name extension will introduce medication errors related to switching between these dosage forms.

Moreover, we have not retrieved any medication errors involving the proprietary name Fycompa. Therefore, given the precedent for using this naming convention, we have no safety concerns with the proposal to market this product with the proprietary name, Fycompa.

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 2, 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 2, 2015, they stated no additional concerns with the proposed proprietary name, Fycompa.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact CDR Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 9, 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. Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

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11/04/2015

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