CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210493Orig1s000

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 14, 2017
Application Type and Number:	NDA 210493
Product Name and Strength:	Akynzeo (fosnetupitant and palonosetron), for injection, 235mg/0.25mg
Product Type:	Multi-ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Helsinn Healthcare, SA
Panorama #:	2017- 14603211
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph.
DMEPA Team Leader (Acting):	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Akynzeo, for fosnetupitant and palonosetron for injection, which was found conditionally acceptable under IND 115191 on March 22, 2017.[a] The Applicant re-submitted the name, Akynzeo, for review under NDA 210493 on April 20, 2017. We note that all product characteristics remain the same.

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 and the Division of Gastroenterology & Inborn Error Products (DGIEP) concurred with the findings of OPDP's assessment of the proposed name.

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. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 30, 2017, search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.2.1 Multiple Dosage Forms Under a Single Proprietary Name

The Applicant is proposing a new dosage form and strength of Akynzeo, 235 mg/0.25 mg lyophilized powder for injection, for intravenous use, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy. We note that Akynzeo is currently approved in a capsule formulation for oral administration and shares the same indication as the proposed formulation.

In our previous review, we evaluated the use of the same proprietary name for the two formulations and found the approach to be acceptable.[b] At the time of our previous review, fosnetupitant and palonosetron for injection was not determined to be a new molecular entity (NME). However, on June 8, 2017, the Office of Pharmaceutical Quality (OPQ) determined that NDA 210493 fosnetupitant and palonosetron for injection is considered to be a New Molecular Entity (NME) based on the following reasons: fosnetupitant represents a "covalently bonded

---

[a]Abraham, S. Proprietary Name Review for Akynzeo. 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); 2017 03 22 Panorama No. 2016-10708323

[b] Abraham, S. Proprietary Name Review for Akynzeo. 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); 2017 03 22 Panorama No. 2016-10708323

modification" to netupitant. Although not all "covalently bonded modifications" are NMEs, fosnetupitant is an ester of N-hydroxymethyl-netupitant, and not an ester of the previously approved active moiety, netupitant, and therefore, is considered a new active moiety. Subsequently, the Division of Gastroenterology and Inborn Errors Products (DGIEP) informed DMEPA that the Applicant was made aware in the filing communication letter (dated June 28, 2017) that NDA 210493 fosnetupitant and palonosetron for injection will be reviewed under PDUFA V program which applies to NMEs.

We consider the naming strategy in light of the NME determination for fosnetupitant and palonosetron, and we determined that fosnetupitant and palonosetron for injection and netupitant and palonosetron oral capsule may share the same proprietary name, Akynzeo, due to the absence of safety concerns. Additionally, there is regulatory precedent established in the case of Emend (NDA 022023), which uses the same naming convention. Emend, the prodrug, fosaprepitant for injection (which was determined to be an NME), shares the same proprietary name as the oral dosage form, aprepitant. We are not aware of any medication errors associated with this naming convention for Emend.

Therefore, for the aforementioned reasons, DMEPA finds the applicant's proposal to use the proprietary name Akynzeo for the injectable formulation acceptable.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Additionally, we did not identify any safety concerns pertaining to use of the same proprietary name for the injectable and oral formulations. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Nicholas Miles, OSE project manager, at (301) 796-7025.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 20, 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.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SHERLY ABRAHAM
07/14/2017

SARAH K VEE
07/14/2017