CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207865Orig1s000

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:	September 29, 2014
Application Type and Number:	NDA 207865
Product Name and Strength:	Emend (aprepitant) for Oral Suspension, 125 mg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Merck & Co., Inc.
Submission Date:	August 8, 2014
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph
DMEPA Team Leader:	Kendra Worthy, Pharm.D.
DMEPA Associate Director:	Lubna Merchant, M.S., Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Emend, from a safety and misbranding perspective. NDA 207865 is a new dosage form (Oral Suspension) for Emend and the Applicant is proposing that this dosage form also be marketed under the proprietary name, Emend. The capsule formulation of Emend (aprepitant) in 40mg, 80mg, and 125 mg was approved on March 27, 2003. The intravenous injection formulation of Emend (aprepitant) was approved on January 25, 2008.

1.1 REGULATORY HISTORY

The product information within, Table 1, is provided in the August 8, 2014, proprietary name submission and proposed prescribing information submitted by Applicant on July 25, 2014.

Products:	**Emend for Oral Suspension** **Proposed**	**Emend Capsules** **Approved 3/2003**	**Emend for Intravenous Injection** **Approved 1/2008**
Active Ingredient:	aprepitant	aprepitant	fosaprepitant dimeglumine
Indication:	For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic and moderately emetogenic cancer chemotherapy) including high-dose Cisplatin. (b) (4)	For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic and moderately emetogenic cancer chemotherapy including high-dose Cisplatin. For prevention of postoperative nausea and vomiting.	For the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic and moderately emetogenic cancer chemotherapy including high-dose Cisplatin.
Route of Admini-stration:	Oral	Oral	Intravenous
Dosage Form:	Powder for Oral Suspension	Capsule	Injection
Strength:	125 mg	40 mg, 80 mg, and	115 mg and 150 mg

		125 mg	
Dose and Frequency	Adults and adolescents: The recommended dose is 125 mg orally on Day 1 and 80 mg orally on Days 2 and 3. Children (aged 6 months to less than 12 years): The recommended dose for oral suspension is based on weight as shown below: less than 6 kg: Not recommended (b) (4)	The recommended dose of EMEND is 125 mg orally 1 hour prior to chemotherapy treatment (Day 1) and 80 mg orally once daily in the morning on Days 2 and 3.	HEC (Single Dose Regimen): EMEND for Injection (150 mg) is administered on Day 1 only as an infusion **over 20-30 minutes** initiated approximately 30 minutes prior to chemotherapy. No capsules of EMEND are administered on Days 2 and 3. HEC and MEC (3-Day Dosing Regimen): EMEND for Injection (115 mg) is administered on Day 1 as an infusion **over 15 minutes** initiated approximately 30 minutes prior to chemotherapy. EMEND capsules (80 mg) are given orally on Days 2 and 3.

	[redacted] (b) (4)		
How Supplied:	Pink to light pink powder, in a single-use pouch, packaged as a kit with one 5 mL dispenser and one mixing cup.	80 mg Cap: Unit-of-use bipack of 2, unit-dose package of 6. 125 mg : unit-dose package of 6, unit of use Tripack containing one 125 mg cap and two 80 mg capsules. 40 mg: unit-of-use package of 1 and unit-dose package of 5.	Single dose vial: 1 vial per carton.
Storage:	Storage: Store at 20 25°C (68-77°F); excursions permitted between 15 30°C (between 59 86°F). Store in the original container. Do not open pouch until ready for use. [redacted] (b) (4)	Storage: Store at 20 25°C (68 -77°F). See USP Controlled Room Temperature.	Store at 2-8°C (36-46°F).
Container and Closure System:	Single-use pouch.	White Plastic [redacted] (b) (4) Closure.	Glass vial closed by a rubber stopper and capped with an aluminum seal and a flip-off plastic cap.

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 does not misbrand the proposed product. DMEPA and the Division of Gastroenterology and Inborn Error Products (DGIEP) 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 did not provide a derivation or intended meaning for the proposed name, Emend, in their submission. 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 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 A for a description of FAERS database) for name confusion errors involving the tablet formulation of Emend. This search did not yield any cases of name confusion with Emend.

Table 2. FAERS Search Strategy	
Date	September 15, 2014
Drug Name(Product Name)	Emend
MedDRA Event Search	Medication Errors-HLGT Product Label Issues-HLT Product Packaging Issues-HLT Product Quality Issues NEC-HLT
Time/Date Limits	July 1, 2013 to September 15, 2014

[1]USAN stem search conducted on September 18, 2014.

2.2.3 Multiple Dosage Forms Under a Single Proprietary Name

Emend is currently marketed as capsules and intravenous injection. Although the intravenous injection and the capsules have some product differences, they are currently managed under the same name. We note that the Emend capsules and the proposed oral suspension share the same active ingredient, same indication, dose and an overlap in one of the strengths. They differ is some characteristics including patient population, and dosage form.

It is a common and accepted practice to have a product line with multiple dosage forms given via different dosage form managed under one proprietary name. We note that the strength and patient population differ between these dosage forms, however these differences can be managed via labeling. There are currently other marketed products available in different strengths administered at different frequencies which are managed safely under one proprietary name. Additionally, there are also risks associated with using dual proprietary names. The use of a new proprietary name for the oral suspension poses a risk of concomitant therapy if practitioners and patients fail to recognize that both products contain aprepitant leading to overdose.

Moreover, we have not retrieved any medication errors involving the proprietary name Emend and other marketed drug products. 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 Emend.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, August 26, 2014, the Division of Gastroenterology and Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastrointestinal and Inborn Error Products (DGIEP) via e-mail on September 23, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on September 29, 2014, they stated no additional concerns with the proposed proprietary name, Emend.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact, Pete Do, OSE project manager, at 301-796-4795.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 8, 2014, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES AND DATABASE DESCRIPTION.

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. ***FDA Adverse Event Reporting System (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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