

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**209472Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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**Date of This Review:** April 28, 2017  
**Application Type and Number:** NDA 209472  
**Product Name and Strength:** Pefexy (pemetrexed) Injection  
25 mg/mL  
**Total Product Strength:** 500 mg/ 20 mL  
**Product Type:** Single Ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Eagle Pharmaceuticals Inc.  
**Panorama #:** 2017-13241140  
**DMEPA Primary Reviewer:** Janine Stewart, PharmD  
**DMEPA Acting Deputy Director:** Danielle Harris, PharmD, BCPS

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Pemfexy, 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 submitted an external name study, conducted by [REDACTED]<sup>(b) (4)</sup>, for this product.

### 1.1 PRODUCT INFORMATION

The following product information is provided in the February 16, 2017 proprietary name submission.

- Intended Pronunciation: Pem-FECKS-ee
- Active Ingredient: pemetrexed
- Indication of Use:
  - Locally Advanced or Metastatic Nonsquamous Non-Small Cell Lung Cancer:
    - Initial treatment in combination with cisplatin.
    - Maintenance treatment of patients whose disease has not progressed after four cycles of platinum-based first-line chemotherapy.
    - After prior chemotherapy as a single-agent.
  - Mesothelioma:
    - in combination with cisplatin.
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 25 mg/mL
- Dose and Frequency: 500 mg/m<sup>2</sup> day 1 of each 21-day cycle (10-minute infusion). [REDACTED]<sup>(b) (4)</sup>
- How Supplied: vials containing 500 mg/ 20 mL of pemetrexed packaged in individual cartons
- Storage: Store at 2°C to 8°C (36°F to 46°F); allow to reach room temperature prior to dose administration
- Container and Closure Systems: glass vials

## 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 Oncology Products 2 (DOP2) 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<sup>a</sup>.

### 2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Pemfexy, incorporates part of the chemical name for pemetrexed injection, pemetrexed diacid or pemetrexed free acid; the “pem-“stem portion. 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, March 1, 2017 e-mail, the Division of Oncology Products 2 (DOP2) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### 2.2.4 *FDA Name Simulation Studies*

Eighty-three practitioners participated in DMEPA’s prescription simulation studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

### 2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search<sup>b</sup> identified 91 names with a combined phonetic and orthographic score of  $\geq 55\%$  or an individual phonetic or orthographic score  $\geq 70$ . These names are included in Table 1 below.

### 2.2.6 *Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

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<sup>a</sup> USAN stem search conducted on March 1, 2017.

<sup>b</sup> POCA search conducted on April 5, 2017 in version 4.0.

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