CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205103Orig1s000

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*****

Date of This Review:	May 26, 2016
Application Type and Number:	NDA 205103
Product Name and Strength:	Yosprala (Aspirin and Omeprazole) Delayed-release Tablets 325 mg/40 mg and 81 mg/40 mg
Product Type:	Multi Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pozen Inc.
Submission Date:	March 14, 2016
Panorama #:	2016- 3056377
DMEPA Primary Reviewer:	Sherly Abraham, R.Ph
DMEPA Team Leader:	Mishale Mistry, Pharm.D.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Yosprala, 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

Pozen submitted the proposed proprietary name, Yosprala, on July 17, 2013, under NDA 205103. On September 12, 2013, Division of Medication Error Prevention and Analysis (DMEPA) conditionally approved the proposed name[1]. However, the Division of Gastroenterology and Inborn Error Products (DGIEP) issued a Complete Response (CR) for the application on April 25, 2014. Pozen re-submitted the NDA to the Division on June 30, 2014, and resubmitted the name, Yosprala, for evaluation on July 21, 2014 per our request. On September 29, 2014, DMEPA conditionally approved the proposed name[2]. On December 16, 2014, another CR letter was issued due to continued manufacturing facility deficiencies. When application was resubmitted on March 14, 2016, the proposed name was also resubmitted for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 14, 2016, proprietary name submission.

- Intended Pronunciation: yo SPRA lah
- Active Ingredient: Aspirin and Omeprazole
- Indication of Use: indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers.

  The aspirin component of YOSPRALA is indicated for:

  - 1) reducing the combined risk of death and nonfatal stroke in patients who have had ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli, 2)reducing the combined risk of death and nonfatal MI in patients with a previous MI or unstable angina pectoris, 3)reducing the combined risk of MI and sudden

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[1] Khosla,L..Proprietary Name Review for Yosprala (NDA 205103). 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); 2013 Sept 12. 10 p. OSE RCM No.: 2013-.1683

[2] Abraham S. Proprietary Name Review for Yosprala (NDA 205103). 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); 2014 Sept 29. 10 p. OSE RCM No.: 2014-25901.

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death in patients with chronic stable angina pectoris, 4)use in patients who have undergone revascularization procedures (Coronary Artery Bypass Graft [CABG] or Percutaneous Transluminal Coronary Angioplasty [PTCA]) when there is a pre-existing condition for which aspirin is already indicated.

The omeprazole component of YOSPRALA is indicated for decreasing the risk of developing aspirin associated gastric ulcers in patients at risk for developing aspirin-associated gastric ulcers due to age (≥ 55) or documented history of gastric ulcers.

- Route of Administration: Oral
- Dosage Form: Delayed-release Tablets
- Strengths: 81 mg delayed release aspirin/40 mg immediate release omeprazole and 325 mg delayed release aspirin/40 mg immediate release omeprazole
- Dose and Frequency: One tablet once daily
- How Supplied: Bottles of 30, 90 (b) (4) tablets
- Storage: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
- Container and Closure Systems: Round shaped bottles, 40 and 60 mL, made of white high density polyethylene (HDPE) with a (b) (4) screw closure (b) (4) (b) (4)

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[3].

[3]USAN stem search conducted on April 20, 2016.

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