CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210563Orig1s000
210563Orig2s000

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:	12/19/2017
Application Type and Number:	NDA 210563
Product Name and Strength:	Imbruvica (ibrutinib) Tablets
Total Product Strength:	140 mg, 280 mg, 420 mg, and 560 mg
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pharmacyclics, Inc.
Panorama #:	2017-17832328
DMEPA Safety Evaluator:	Casmir Ogbonna, PharmD, MBA, BCPS, BCGP
DMEPA Team Leader:	Hina Mehta, PharmD
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Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Imbruvica, 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

Imbruvica (ibrutinib) was approved under NDA 205552 on November 13, 2013 as 140 mg capsules and is indicated for the treatment of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy, chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), CLL/SLL with 17p deletion, Waldenstrom's macroglobuminemia, marginal zone lymphoma who require systemic therapy and have received at least one prior anti-CD20-based therapy, and chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy. The Applicant proposes a tablet dosage form in strengths of 140 mg, 280 mg, 420 mg, and 560 mg, intended to be marketed for the treatment of the same approved indications as the currently approved capsule formulation. Thus, the Applicant submitted the name, Imbruvica, for the new dosage form under review for NDA 210563 on September 28, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 28, 2017, proprietary name submission.

Table 1. Relevant Product Information for Imbruvica

Product	**Imbruvica (NDA 210563)**	**Imbruvica (NDA 205552)**
Initial Approval Date	Currently under review.	November 13, 2013
Active Ingredient	Ibrutinib	
Indication	Imbruvica is a Bruton's Tyrosine Kinase Inhibitor indicated for: • treatment of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy • chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) • CLL/SLL with 17p deletion • Waldenstrom's macroglobuminemia (WM) • Marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy • chronic graft versus host disease (cGVHD) after failure of one or more lines of systemic therapy	
Route of Administration	Oral	
Dosage Form:	Tablets	Capsules
Strength:	140 mg, 280 mg, 420 mg, 560 mg	140 mg

Dose and Frequency	MCL and MZL: 560 mg taken orally once daily CLL/SLL, WM, and cGVHD: 420 mg taken orally once daily	
How Supplied:	140 mg tablet: yellow green to green round tablets debossed with "ibr" on one side and "140" on the other side. 2 blisters of 14 count NDC 57962-014-28 280 mg tablet: purple oblong tablets debossed with "ibr" on one side and "280" on the other side. 2 blisters of 14 count NDC 57962-280-28 420 mg tablet: yellow green to green oblong tablets debossed with "ibr" on one side and "420" on the other side. 2 blisters of 14 count NDC 57962-420-28 560 mg tablet: yellow to orange oblong tablets debossed with "ibr" on one side and "560" on the other side. 2 blisters of 14 count NDC 57962-560-28	The white opaque 140 mg capsules marked with "ibr 140 mg" in black ink are available in white HDPE bottles with a child-resistant closure: • 90 capsules per bottle: NDC 57962-140-09 • 120 capsules per bottle: NDC 57962-140-12
Storage:	Store bottles at room temperature 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F to 86°F). Retain in original package.	

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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Division of Hematology Products (DHP) 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.

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