CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205552Orig2s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	August 15, 2013
Reviewer:	Kevin Wright, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Yelena Maslov, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Imbruvica (Ibrutinib) Capsules 140 mg
Application Type/Number:	NDA 205552
Applicant/Sponsor:	Pharmacyclics, Inc.
OSE RCM #:	2013-1060

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Imbruvica, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 PRODUCT INFORMATION

The following product information is provided in the July 12, 2013 proprietary name submission.

- Intended pronunciation: Im-broo-vik-Ə
- Indication of Use: is a Bruton tyrosine kinase inhibitor indicated for the treatment of mantle cell lymphoma, chronic lymphocytic leukemia, and small lymphocytic lymphoma in patients who have received at least one prior therapy.
- Route of Administration: Oral
- Dosage Form: Capsule
- Strength: 140 mg
- Dose and Frequency:
    - Mantel cell lymphoma: 560 mg orally daily
    - Chronic Lymphocytic Leukemia and Small Lymphocytic Lymphoma: 420 mg orally daily
    - Dose Adjustment

Toxicity Occurrence	Mantle cell lymphoma Modification after Recovery	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma after Recovery
First	Restart at 560 mg daily	Restart at 420 mg daily
Second	Restart 420 mg daily	Restart at 280 mg daily
Third	Restart at 280 mg daily	Restart 140 mg daily
Fourth	Discontinue therapy	

- How Supplied: 90 and 120 count bottles
- Storage: store between 20° to 25°C(68° to 77°F); excursions permitted between 15° to 30° C (59° to 86°F)
- Container and Closure System: High density polyethylene (HDPE) bottles of 90 and 120 capsules

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's promotional 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 indicated in their submission that the proposed name, Imbruvica, has no listed derivation or intended meaning. This proprietary name is comprised of a single word that does not contain any components such as a modifier, route of administration, dosage form.

2.2.3 FDA Name Simulation Studies

Forty-seven practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. In the written studies, 19 of 32 participants correctly interpreted the prescription. Common misinterpretations in the written study were substitution of 'ch', for 'im' and 'r' for 'c'. In the voice study 6 of 29 participants correctly interpreted the prescription. Common misinterpretations in the voice study include: 'em', for 'im' and 'pr' for 'br'. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). Appendix C contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, July 25, 2013 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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[1] USAN stem search conducted August 1, 2013.

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