CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210563Orig1s000
210563Orig2s000

OTHER REVIEW(S)

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

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)

Date of This Memorandum:	February 15, 2018
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 210563
Product Name and Strength:	Imbruvica (ibrutinib) tablets, 140 mg, 280 mg, 420 mg, and 560 mg
Applicant/Sponsor Name:	Pharmacyclics LLC
FDA Received Date:	February 14, 2018
OSE RCM #:	2017-1815-2
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMO

The Division of Hematology Products (DHP) requested that we review the revised carton labeling and blister pack labeling for Imbruvica tablets (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The revised carton labeling and blister pack labeling for Imbruvica tablets is acceptable from a medication error perspective. We have no further recommendations at this time.

8 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[a] Garrison N. Label and Labeling Review Memo for IMBRUVICA (NDA 210563). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 FEB 07. RCM No.: 2017-1815-1.

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/s/

NICOLE B GARRISON
02/15/2018

HINA S MEHTA
02/15/2018

MEMORANDUM

REVIEW OF REVISED LABEL AND LABELING

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)

Date of This Memorandum:	February 7, 2018
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 210563
Product Name and Strength:	Imbruvica (ibrutinib) tablets, 140 mg, 280 mg, 420 mg, and 560 mg
Applicant/Sponsor Name:	Pharmacyclics LLC
FDA Received Date:	January 22, 2018
OSE RCM #:	2017-1815-1
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMO

The Division of Hematology Products (DHP) requested that we review the revised carton labeling and blister pack labeling for Imbruvica tablets (Appendix A) to determine if it is acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

The revised carton labeling and blister pack labeling is unacceptable from a medication error perspective. For the carton labeling, there is inadequate differentiation between the 140 mg capsule strength (b) (4) and the 420 mg tablet strength (b) (4).

In our previous label and labeling review for Imbruvica tablets, we recommended deletion of (b) (4) on the blister pack labeling (b) (4) (b) (4). The Sponsor acknowledged our concern, however; based upon several market research studies they conducted with patients, nurses, pharmacists, and distributors, (b) (4) labeling was

[a] Garrison N. Label and Labeling Review for Imbruvica (NDA 210563). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 11. RCM No.: 2017-1815.

the preferred package configuration [redacted]. We acknowledge the Sponsor's response to our information request, but provide additional revisions to the blister pack labeling. As currently presented, the blister pack labeling may potentially confuse the intended users and differs from other available dose packs.

3 RECOMMENDATIONS FOR PHARMACYCLICS LLC

We recommend the following be implemented prior to approval of this NDA:

A. Carton labeling

There is inadequate differentiation between the 140 mg capsule strength [redacted] and the 420 mg tablet strength [redacted]). Revise the color scheme of the 420 mg tablet strength [redacted], so that it appears in its own unique color and the color does not overlap with any other colors utilized in highlighting the strengths. The use of the same [redacted] scheme for the product's 140 mg capsule and 420 mg tablet strengths minimizes the difference between the strengths, which may lead to wrong strength selection errors.

B. Blister pack labeling

1. We recommend deleting [redacted] in the blister pack as this may confuse the intended user.
2. For increased clarity, we recommend [redacted]
3. We also recommend deleting [redacted].
4. Add the proprietary name, established name, and product strength from the back of the blister pack labeling to the front of the blister pack labeling. In addition, revise the product strength to display the strength per tablet (e.g. 560 mg per tablet).

7 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

[b] Response to Information Request received on January 22, 2018.

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