CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205580Orig1s000

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:	March 30, 2018
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 205580
Product Name and Strength:	Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL)
Applicant/Sponsor Name:	Eagle Pharmaceuticals
FDA Received Date:	March 20, 2018
OSE RCM #:	2018-283-1
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 PURPOSE OF MEMORANDUM

The Division of Hematology Products (DHP) requested that we review the revised container labels and carton labeling for Bendamustine Hydrochloride (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] We note per email response; the Applicant intends to market the product with the established name, bendamustine hydrochloride for now[b].

2 CONCLUSION

The revised container labels and carton labeling are acceptable from a medication error perspective.

[a] Garrison N. Label and Labeling Review for Bendamustine Hydrochloride (NDA 205580). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 MAR 13. RCM No.: 2018-283.

[b] Information Request Response received on March 30, 2018.

APPENDIX A. IMAGES OF LABEL AND LABELING RECEIVED ON MARCH 20, 2018

Container labels

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

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NICOLE B GARRISON
03/30/2018

HINA S MEHTA
03/30/2018

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:	March 13, 2018
Requesting Office or Division:	Division of Hematology Products (DHP)
Application Type and Number:	NDA 205580
Product Name and Strength:	Belrapzo (bendamustine hydrochloride) Injection, 100 mg/4 mL (25 mg/mL)
Applicant/Sponsor Name:	Eagle Pharmaceuticals
FDA Received Date:	January 31, 2018 and February 9, 2018
OSE RCM #:	2018-283
DMEPA Safety Evaluator:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Associate Director (Acting):	Mishale Mistry, PharmD, MPH

1 PURPOSE OF MEMO

The Division of Hematology Products (DHP) requested that we review the proposed container label, carton labeling, and Prescribing Information (PI) for Bendamustine Injection (NDA 205580) for areas of vulnerability that may lead to medication errors (Appendix A). DHP requested this review as a part of their evaluation of the 505(b)(2) NDA class I resubmission for Bendamustine Injection. DMEPA provided recommendations during a previous label and labeling review.[a,b]

1.1 REGULATORY HISTORY

[a] Gao. T. Label, Labeling and Packaging Review for Bendamustine (NDA 205580). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2013 DEC 24. RCM No.: 2013-1791.

[b] Gao. T. Label, Labeling Review Memo for Bendamustine (NDA 205580). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 APR 09. RCM No.: 2013-1791.

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