CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022561Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	August 14, 2018
Application Type and Number:	NDA 022561
Product Name and Strength:	Mavenclad (cladribine) tablet, 10 mg
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	EMD Serono, Inc.
Panorama #:	2018-23509491
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Mavenclad, which was found conditionally acceptable under IND 074634 on December, 13, 2017.[a] We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 13, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on August 8, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on August 14, 2018, they stated no additional concerns with the proposed proprietary name, Mavenclad.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Mavenclad, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on June 4, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[a] Morris, C. Proprietary Name Review for Mavenclad (IND 074634). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 DEC 13. Panorama No. 2017-16491421.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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/s/

JOHN C MORRIS
08/15/2018

LOLITA G WHITE
08/15/2018

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	February 23, 2011
Application Type/Number:	NDA 022561
Through:	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Irene Z. Chan, Pharm.D., BCPS, Acting Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	(b) (4) (Cladribine) Tablets, 10 mg
Applicant:	EMD Serono
OSE RCM #:	2010-2278

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/s/

IRENE Z CHAN
02/23/2011

CAROL A HOLQUIST
02/23/2011

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	July 30, 2010
To:	Russell Katz, M.D., Director Division of Neurology Products
Through:	Melina Griffis, RPh, Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Irene Z. Chan, Pharm.D., BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	(b) (4) (Cladribine) Tablet, 10 mg
Application Type/Number:	NDA 022561
Applicant/Applicant:	EMD Serono
OSE RCM #:	2010-1239

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22561	ORIG-1	EMD SERONO INC	CLADRIBINE

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/s/

IRENE Z CHAN
07/30/2010

DENISE P TOYER on behalf of MELINA N GRIFFIS
07/30/2010

DENISE P TOYER
07/30/2010

CAROL A HOLQUIST
07/30/2010