CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219685Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	December 4, 2024
Application Type and Number:	NDA 219685
Product Name, Dosage Form, and Strength:	Wayrilz (rilzabrutinib) tablet, 400 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Genzyme Corporation (Genzyme)
PNR ID #:	2024-1044725989
DMEPA 2 Safety Evaluator:	Sue Black, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Wayrilz, which was found conditionally acceptable under IND 132668 on August 20, 2024.[a]

Thus, Genzyme submitted the proposed proprietary name, Wayrilz, under NDA 219685 for re-review on September 17, 2024.[b] We note that there are changes in product characteristics (e.g., specification of indication, dosing information for hepatic impairment and drug interactions, additional supply presentation and storage information) for NDA 219685. All other product characteristics remain the same.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Wayrilz would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Wayrilz. The Division of Non-Malignant Hematology (DNH) did not comment on the findings of OPDP's assessment for Wayrilz.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Wayrilz, we 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. We also evaluated previously identified names taking into account the changes in product characteristics:

Table 1. Changes in Product Characteristics		
	Wayrilz[c] (previous IND 132668 submission)	Wayrilz[d] (current NDA 219685 submission)
Indication	Immune Thrombocytopenia (ITP)	Treatment of adult patients with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response (b) (4) to a previous treatment
Dose and Frequency	400 mg tablet orally twice daily	400 mg taken orally twice daily

[a] Black, S. Proprietary Name Review for Wayrilz (IND 132668). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 20. PNR ID No. 2024-1044725653.

[b] Request for Proprietary Name (NDA 219685 and Wayrilz). Cambridge (MA): Genzyme Corporation; 2024 SEP 17. Available from: \\CDSESUB1\EVSPROD\nda219685\0002\m1\us\proprietary-name-wayrilz.pdf.

[c] Black, S. Proprietary Name Review for Wayrilz (IND 132668). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 AUG 20. PNR ID No. 2024-1044725653.

[d] Proposed Prescribing Information (Wayrilz and NDA 219685). Cambridge (MA): Genzyme Corporation; 2024 AUG 29. Available from: \\CDSESUB1\EVSPROD\nda219685\0001\m1\us\proposedpi.pdf.

		Avoid use in patients with moderate or severe hepatic impairment. Dose modification is not required for patients with mild hepatic impairment. Avoid co-administration with moderate or strong CYP3A inhibitors, moderate or strong CYP3A inducers and proton pump inhibitors (PPIs). If treatment with a gastric acid reducing agent is required, consider using a H2-receptor antagonist (H2RA). Take Wayrilz at least 2 hours before taking the H2RA.
How Supplied	This product will be supplied as 60-count HDPE bottles (b) (4) (b) (4) capped with a child resistant closure, and induction sealed.	<table><tr><th>Package Size/Type</th><th>Content</th><th>NDC Number</th></tr><tr><td>60-count bottle</td><td>Bottle containing 60 film-coated tablets with a child-resistant closure</td><td>58468-0251-6</td></tr><tr><td>56-count carton</td><td>Carton containing 2 blister packs, each containing (b) (4) (58468-0251-0) (b) (4) 28 film-coated tablets each</td><td>58468-0251-5</td></tr></table>
Storage	(b) (4)	Store in original packaging between 20°C to 25°C (68°F to 77°F); excursions are permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from light and moisture.

Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Wayrilz.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The October 17, 2024 search of USAN stems did not find any USAN stems in the proposed proprietary name, Wayrilz.

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On December 4, 2024, DMEPA 2 communicated our determination to the Division of Non-Malignant Hematology (DNH).

3 CONCLUSION

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, Wayrilz, is conditionally acceptable.

3.1 COMMENTS TO GENZYME CORPORATION

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

If any of the proposed product characteristics as stated in your submission, received on September 17, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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