CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208399Orig1s000

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:	July 18, 2017
Application Type and Number:	NDA 208399
Product Name and Strength:	Varubi (rolapitant) injectable emulsion, 166.5 mg/92.5 mL (1.8 mg/mL)
Total Product Strength:	166.5 mg/92.5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Tesaro, Inc.
Panorama #:	2017-14656187
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Sarah K. Vee, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Varubi, which was found conditionally acceptable under NDA 208399 on July 19, 2016.[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 Gastroenterology & Inborn Error Products (DGIEP) 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 21, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 Nicholas Miles, OSE project manager, at 301-796-7025.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your April 25, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[a] Barlow, M. Proprietary Name Review for Varubi (NDA 208399). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 JUL 19. Panorama No. 2016-7798120.

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/

MATTHEW J BARLOW
07/18/2017

SARAH K VEE
07/18/2017

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
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Date of This Review:	July 19, 2016
Application Type and Number:	NDA 208399
Product Name and Strength:	Varubi (rolapitant) Injectable Emulsion, 166.5 mg/92.5 mL (1.8 mg/mL)
Total Product Strength:	166.5 mg/92.5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Tesaro, Inc.
Panorama #:	2016-7798120
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Varubi, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Varubi (rolapitant hydrochloride) oral tablet was approved on September 1, 2015, under NDA 206500. The applicant submitted the name, Varubi, for a new dosage form, injectable emulsion, under review for NDA 208399 on April 29, 2016. The applicant submitted an amendment to their request for proprietary name review on May 9, 2016.

1.2 PRODUCT INFORMATION

The following product information is provided in the May 9, 2016 proprietary name submission and prescribing information labeling submitted on June 24, 2016.

Table 1. Relevant Product Information for Varubi		
Product	**Varubi (NDA 208399)**	**Varubi (NDA 206500)**
Pronunciation	va' roo bee	
Initial Approval Date	Currently under review.	September 1, 2015
Active Ingredient	rolapitant hydrochloride	
Indication	Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.	
Route of Administration	Intravenous	Oral
Dosage Form:	Injection Emulsion	Tablets
Strength:	166.5 mg/ 92.5 mL (1.8 mg/ mL)	90 mg
Dose and Frequency	166.5 mg infused over 30 minutes within 2 hours prior to initiation of chemotherapy	180 mg administered orally within 2 hours prior to initiation of chemotherapy
How Supplied:	Sterile, translucent white homogenous emulsion in a stoppered (b) (4) single-dose vial. Each vial delivers 166.5 mg rolapitant in 92.5 mL	Film-coated, capsule shaped, blue tablets, debossed with T0101 on one side and 100 on the other side. Each tablet contains 90 mg rolapitant.

		VARUBI tablets are packaged in an Aclar blister shell with aluminum foil backing and supplied as a single-dose package.
Storage:	Store at 20ºC to 25ºC (68ºF to 77ºF); excursions are permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].	

2 RESULTS

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

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 Gastroenterology & Inborn Error Products (DGIEP) concurred with the findings of OPDP's 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 did not provide a derivation or intended meaning for the proposed name, Varubi in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, May 11 2016 e-mail, the Division of Gastroenterology & Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[1]USAN stem search conducted on July 7, 2016.

2.2.4 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Varubi will be available in strength of 166.5 mg. Since this is not a typical strength that is not commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Varubi that were not identified in POCA, and found to have an overlap in strength with Varubi. Our search of the eDLRS database yielded no results.

2.2.5 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Varubi that would be relevant for this review. This search did not yield any cases of name confusion with Varubi.

Table 2. FAERS Search Strategy

Search Date	July 7, 2016
Drug Name	Varubi (rolapitant hydrochloride)
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED

	WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	September 1, 2015 to July 7, 2016

2.2.6 Multiple Dosage Forms Under a Single Proprietary Name

The Applicant is proposing a new dosage form and strength of Varubi, a 166.5 mg/92.5 mL injectable emulsion in a single-dose vial, for the prevention of chemotherapy induced nausea and vomiting (CINV) in their submission under NDA 208399. We note that the currently approved Varubi shares the same active ingredient and indication. The two formulations differ in some characteristics, including strength, dosage form, and route of administration. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name. Differences in strength, dosage form, and route of administration can be managed via labeling.

Moreover, we have not retrieved any medication errors involving the proprietary name Varubi. Therefore, given the precedent for using this naming convention, and the absence of any medication errors involving the proprietary name, we find the Applicant's proposal to market the proposed product with the proprietary name Varubi acceptable.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology & Inborn Error Products (DGIEP) via e-mail on July 15, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DGIEP on July 18, 2016, they stated no additional concerns with the proposed proprietary name, Varubi.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 9, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

2. ***Electronic Drug Registration and Listing System (eDRLS) database***

   The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. **Preliminary Assessment:** We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[2]

[2] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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/s/

MATTHEW J BARLOW
07/19/2016

MISHALE P MISTRY
07/19/2016