

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

209241Orig1s000

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:	November 14, 2016
Application Type and Number:	NDA 209241
Product Name and Strength:	Ingrezza (valbenazine) capsule, 40 mg
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Neurocrine Biosciences, Inc.
Panorama #:	2016-9845506
DMEPA Primary Reviewer:	Ebony Whaley, PharmD, BCPPS
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ingrezza, which was found conditionally acceptable under IND 111591 on June 23, 2016.^a

We note that there is a change in the established name for NDA 209241. All other 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 Psychiatry Products (DPP) 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. We also evaluated previously identified names taking into account the change in established name from [REDACTED]^{(b) (4)} to 'valbenazine capsules'. We confirmed with DPP that the change in established name will not affect the strength or dose presentation of the product. Our evaluation has not 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 September 22, 2016 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 from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE project manager, at 240-402-5035.

3.1 COMMENTS TO THE APPLICANT

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

^a Harris, D. Proprietary Name Review for Ingrezza IND 111591. 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 JUN 22. Panorama No. 2016-7665967.

If any of the proposed product characteristics as stated in your August 25, 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.

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

/s/

EBONY A WHALEY
11/13/2016

LOLITA G WHITE
11/13/2016