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APPLICATION NUMBER:

208745Orig1s000

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: September 8, 2016
Application Type and Number: NDA 208745
Product Name and Strength: Trulance (plecanatide) Oral Tablets, 3 mg
Product Type: Single Ingredient Product
Rx or OTC: Rx
Applicant/Sponsor Name: Synergy Pharmaceuticals
Panorama #: 2016-2862855-1
DMEPA Primary Reviewer: Matthew Barlow, RN, BSN
DMEPA Team Leader: Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Trulance, based the revised strength and dose. The proposed proprietary name, Trulance, was found conditionally acceptable under IND (b)(4) and NDA 208745 on May 11, 2016.^a We previously reviewed the product with (b)(4) dose of 3 mg (b)(4) taken once daily with or without food. During review of the application, the proposed strength is 3 mg and the proposed dose is 3 mg taken once daily with or without food.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in strength and dose. 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 August 30, 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 Ginneh Stowe, OSE project manager, at 301-796-4049.

^a [Barlow, M]. Proprietary Name Review for [Trulance (NDA 208745 & IND (b)(4))]. 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 May 16]. Panorama No. [2016-2862855].

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
09/08/2016

MISHALE P MISTRY
09/08/2016

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