CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208398Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 208398

PROPRIETARY NAME REQUEST
CONDITIONALLY ACCEPTABLE

Janssen Pharmaceuticals, Inc.
920 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602

ATTENTION: Andrea F. Kollath, DVM
Director, Global Regulatory Affairs

Dear Dr. Kollath:

Please refer to your New Drug Application (NDA) dated April 19, 2016, received April 19, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mebendazole Chewable Tablets, 500 mg.

We also refer to your April 29, 2016, correspondence, received April 29, 2016, requesting review of your proposed proprietary name, Vermox Chewable.

We have completed our review of the proposed proprietary name, Vermox Chewable and have concluded that it is conditionally acceptable.

If any of the proposed product characteristics as stated in your April 29, 2016, submission are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

If you require information on submitting requests for proprietary name review or PDUFA performance goals associated with proprietary name reviews, we refer you to the following:

- Guidance for Industry Contents of a Complete Submission for the Evaluation of Proprietary Names (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075068.pdf)
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, (http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf)

If you have any questions regarding the contents of this letter or any other aspects of the proprietary name review process, contact Janet G. Higgins, Safety Regulatory Project Manager in the Office of Surveillance and Epidemiology, at (240) 402-0330. For any other information

regarding this application, contact Alison Rodgers, Regulatory Project Manager, in the Office of New Drugs at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

Todd Bridges, RPh
Director
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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/s/

TODD D BRIDGES
06/02/2016

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:	May 26, 2016
Application Type and Number:	NDA 208398
Product Name and Strength:	Vermox Chewable (mebendazole) Chewable Tablets, 500 mg
Product Type:	(b) (4)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Janssen Pharmaceuticals, Inc.
Panorama #:	2016-7793829
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Vicky Borders-Hemphill, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Vermox Chewable, which was found conditionally acceptable under IND 115959 on December 11, 2015.[1]

We note that there is a change in the Indications and Usage from (b) (4) IND 115959 to (b) (4) for NDA 208398. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

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 May 4, 2016 search of USAN stems did not find any USAN stems in 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 Anti-Infective Products (DAIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 Medication Error Data Selection of Cases

An updated search of the FDA Adverse Event Reporting System (FAERS) database (date range September 2, 2015 to May 6, 2016) using the same criteria as listed in the previous review[1] did not identify any name confusion error cases that were relevant for this review.

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 Janet Higgins, OSE project manager, at 240-402-0330.

3.1 COMMENTS TO THE APPLICANT

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

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[1] Sheppard, J. Proprietary Name Review for Vermox Chewable (IND 115959). 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); 2015 DEC 11. 18 p. Panorama No. 2015-1115400.

If any of the proposed product characteristics as stated in your April 29, 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.

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/s/

DEBORAH E MYERS
05/26/2016

BRENDA V BORDERS-HEMPHILL
05/31/2016