CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208246Orig1s000

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:	June 24, 2015
Application Type and Number:	NDA 208246
Product Name and Strength:	Xeljanz XR (Tofacitinib) (b) (4) Tablets 11 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer
Panorama #:	2015-328681
DMEPA Primary Reviewer:	Teresa McMillan, PharmD
DMEPA Team Leader:	Kendra Worthy, PharmD
Associate Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Xeljanz XR. DMEPA previously found the name acceptable in OSE Review No. 2014-16866[1] , dated June 24, 2014. We note that (b) (4) have been added since our last review. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA conducted a gap search in the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 1 for name confusion errors involving Xeljanz which would be relevant for this review. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our FAERS search identified one medication error case; however, this medication error case did not represent a potential source of drug name confusion.

Table 1. FAERS Search Strategy

Date	**June 18, 2014 –June 18, 2015 Dated from the last Xeljanz FAERS search in OSE Review #2014-16866**
Drug Name(Product Name)	Xeljanz [product name] Tofacitinib [active ingredient}
MedDRA Event Search	**DMEPA Official Proprietary Name Review Search Terms Event List:** Product name confusion (PT) Medication error (PT) Intercepted medication error (PT) Drug dispensing error (PT) Intercepted drug dispensing error (PT) Circumstance or information capable of leading to a medication error (PT)

Also, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The June 18, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

[1] McMillan, T. Proprietary Name Review for Xeljanz XR (IND 117389). 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); 2014 JUN 24 9p. OSE RCM No. 2014-16866.

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) concurred with the findings of OPDP's promotional assessment of the proposed name.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Neil Vora, OSE Project Manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT/SPONSOR

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

If any of the proposed product characteristics as stated in your April 30, 2015 submission is altered, the name must be resubmitted for review.

4 REFERENCES

1. McMillan, T. Proprietary Name Review for Xeljanz XR (IND 117389). 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); 2014 JUN 24 9p. OSE RCM No. 2014-16866

2. ***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.

3. **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/

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