

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review--Final

Date: October 11, 2012

Reviewer(s): Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Xeljanz (Tofacitinib) Tablets, 5 mg

Application Type/Number: NDA 203214

Applicant/sponsor: Pfizer

OSE RCM #: 2012-1197

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Xeljanz is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Xeljanz, acceptable in OSE Review 2012-801 dated May 21, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-801. We note that the proposed product characteristics were altered. (b) (4)

(b) (4) the 5 mg strength will be approved. Therefore, we re-reviewed the previously identified names of concern in OSE Review 2012-801 using the revised product characteristics. Additionally, we also re-reviewed these names considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded two new names ((b) (4) and (b) (4)), thought to look similar to Xeljanz and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Xeljanz and lead to medication errors. This analysis determined that the name similarity between Xeljanz and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 5, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on August 3, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Xeljanz, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Xeljanz, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Pulmonary, Allergy, and Rheumatology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904.

4 REFERENCES

1. Owens, L., OSE Reviews # 2012-801, Proprietary name review for Xeljanz (NDA 203214), May 21, 2012
2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. *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.
4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: FMEA Table

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg</p> <p>Usual Dose: One tablet by mouth twice daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
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(b) (4)

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/s/

LISSA C OWENS
10/11/2012

LUBNA A MERCHANT
10/11/2012

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: May 21, 2012

Reviewer(s): Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader Lubna Merchant, M.S., PharmD
Division of Medication Error Prevention and Analysis

Division Director Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Xeljanz (Tofacitinib) Tablets, 5 mg and 10 mg

Application Type/Number: NDA 203214

Applicant/Sponsor: Pfizer

OSE RCM #: 2012-801

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Xeljanz, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

This product was reviewed under the proposed name, (b) (4) under the IND in OSE RCM # 2010-2480, dated May 9, 2011, and was found conditionally acceptable at that time. It was then evaluated under the NDA in OSE RCM# 2011-4192 and found unacceptable.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 30, 2012 proprietary name submission.

- Established Name: Tofacitinib
- Indication of Use: Treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one of more disease modifying anti-rheumatic drugs (DMARDs)
- Route of administration: Oral
- Dosage form: Tablets
- Strengths: 5 mg and 10 mg
- Dose and Frequency: 5 mg or 10 mg twice a day orally with or without food
- How Supplied: Bottles of 60 tablets and 180 tablets; 10-count unit-dose blisters in boxes of 60 and 180 tablets for institutional use.
- Storage: 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F)
- Container and Closure systems:
60 mL HDPE bottles with desiccant and 28 mm (b) (4) Caps with induction liners;
120 mL HDPE bottles with desiccant and 38 mm (b) (4) Caps with induction liners;
and foil/foil blisters

2. RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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 concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall safety evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

On May 4, 2012 the United States Adopted Name (USAN) stem search, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The applicant stated that ‘Xeljanz’ is an invented word with no inherent meaning. This proposed 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.

2.2.4 FDA Name Simulation Studies

38 practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Twelve (n=12) participants interpreted the name correctly (n=11; inpatient study, n=1; outpatient study). Common misinterpretations included interpreting the name as ‘Xeljeny’ (n=3; outpatient study) and ‘Xeljenz’ (n=3; outpatient study). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE, April 5, 2012 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Xeljanz. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Xeljanz identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation and by ^{(b) (4)} not identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and (b) (4))

Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
X-Troazine LA	FDA	Xeloda	Both	(b) (4)	FDA
Pergolide	(b) (4)	Xalatan	Both	Salagen	Both
Zetia		Xolair	FDA	Invanz	(b) (4)
Zirgan		Xifaxan	FDA	Relenza	
(b) (4)	FDA	Zuplenz	FDA	Xanax	
Xalcom	FDA	Velban	(b) (4)	Xenazine	
Xologel	FDA	Reyataz		Xenical	
Zelapar	FDA	Xalkori	FDA		
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Xeljanz	FDA	Propofol	(b) (4)	Sitagliptan	(b) (4)
Delsym	(b) (4)				
Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>		
Xylocaine	(b) (4)	Xyzal	(b) (4)		

Our analysis of the twenty-nine names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined none of the names pose a risk for confusion as described in Appendix D through E.

2.2.7 Communication of DMEPA’s Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products via e-mail on May 7, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) on May 14, 2012, they stated no additional concerns with the proposed proprietary name, Xeljanz.

2 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Nichelle Rashid, OSE project manager, at 301-796-3904

2.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Xeljanz, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your March 30, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

3 REFERENCES

1. ***Micromedex Integrated Index*** (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO***
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. ***Drugs@FDA*** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. Red Book (www.thomsonhc.com/home/dispatch)

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. Medical Abbreviations (www.medilexicon.com)

Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names possess similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

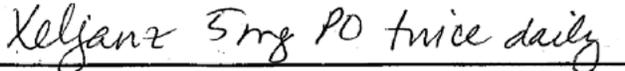
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, NAME	Scripted May Appear as	Spoken May Be Interpreted as
X	d,f,K,P,t,U,V,Y	KS,KZ,S,Z
e	a,i,l,o,u,p	Any vowel
l	b,e,s,A,P,i	none
j	g,p,q,y	none
a	e,el,ci,cl,d,o,u	Any vowel
n	m,u,x,r,h,s	dn,gn,kn,mn,pn,m
z	c,e,g,n,m,q,r,s,v	c,s,x

Appendix C: Prescription Simulation Samples and Results

Figure 1. Xeljanz Study (Conducted on April 6, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> </p> <p><u>Outpatient Prescription:</u> </p>	<p>Xeljanz 10 mg #60 1 po bid</p>

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Xeljanz

	Total	13	10	15
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
VITEX	0	1	0	1
XEJANZ	1	0	0	1
XELIGANZ	1	0	0	1
XELIZIM	0	0	1	1
XELJAMY	0	0	2	2
XELJANY	0	0	1	1
XELJANZ	11	0	1	12
XELJEMY	0	0	2	2
XELJENG	0	0	1	1
XELJENY	0	0	3	3
XELJENZ	0	0	3	3
XELYANG	0	0	1	1
ZALSAN	0	1	0	1
ZELSAN	0	1	0	1
ZELSANDS	0	1	0	1
ZELSANS	0	1	0	1
ZELZANT	0	2	0	2
ZO SANS	0	1	0	1
ZOUTZAND	0	1	0	1
ZOVZAN	0	1	0	1

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Xeljanz	Failure preventions
X-Troazine LA	Phendimetrazine Tartrate	Look	The pair have sufficient orthographic differences
Xeljanz	Tofacitinib	Look and Sound	Subject of this review
Delsym	Dextromethorphan Hydrobromide	Look and Sound	The pair have sufficient orthographic and phonetic differences
Pergolide	Pergolide Mesylate	Look	The pair have sufficient orthographic differences
Propofol	Propofol	Look and Sound	The pair have sufficient orthographic and phonetic differences
Sitagliptin	Sitagliptin Phosphate	Look and Sound	The pair have sufficient orthographic and phonetic differences
Xylocaine	Lidocaine Hydrochloride	Sound	The pair have sufficient phonetic differences
Xyzal	Levocetirizine	Sound	The pair have sufficient phonetic differences
Zetia	Ezetimibe	Look	The pair have sufficient orthographic differences
Zirgan	Ganciclovir	Look	The pair have sufficient orthographic differences
(b) (4)			
Xalcom	Lantanoprost and Timolol Maleate	Look	Product marketed in Europe.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

<p>Proposed name: Xeljanz (Tofacitinib) Dosage Form(s): Tablet Strength(s): 5 mg and 10 mg Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xolegel (Ketoconazole) Gel, 2% <u>Usual dose:</u> Apply to affected area once daily for 2 weeks</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Xol’ <u>Frequency:</u> Both once daily</p>	<p><u>Orthographic:</u> The ending letter strings, ‘anz’ vs. ‘gel’ may look different when scripted due to the upstroke letter ‘l’ at the end of Xolegel which give the pair different shapes. <u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted. There are no overlapping strengths or numerical similarity. <u>Dose:</u> 1 tablet vs. Apply</p>
<p>Zelapar (Selegiline Hydrochloride) Oral disintegrating Tablet, 1.25 mg <u>Usual dose:</u> 1 to 2 tablets by mouth once daily</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Zel’ <u>Dosage Form and Route:</u> Both are tablets and oral <u>Frequency:</u> Both once daily</p>	<p><u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted. There are no overlapping strengths or numerical similarity.</p>
<p>Xeloda (Capecitabine) Tablets, 150 mg, 500 mg <u>Usual dose:</u> One tablet by mouth twice daily</p>	<p><u>Orthographic:</u> Both have the same beginning letter strings, ‘Xel’ <u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> The ending letter strings, ‘anz’ vs. ‘oda’ may look different when scripted due to the upstroke letter ‘d’ in the 5th position in Xeloda which give the pair different shapes. <u>Strength:</u> Both are multiple strength products which must be indicated on the prescription and there are no overlapping strengths.</p>

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg and 10 mg</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xalatan (Latanoprost) Ophthalmic Solution, 0.005%</p> <p><u>Usual Dose:</u> One drop into each eye once a day</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Xal’</p> <p><u>Frequency:</u> Both once daily</p>	<p><u>Orthographic:</u> The ending letter strings, ‘anz’ vs. ‘tan’ may look different when scripted due to the cross-stroke letter ‘t’ in the 5th position in Xalatan vs. Xeljanz which has no cross-stroke letters. Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Xalatan which has no downstroke letters.</p> <p><u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted. There are no overlapping strengths or numerical similarity.</p>
<p>Xolair (Omalizumab) Injection, 150 mg/5 mL</p> <p><u>Usual dose:</u> 150 mg to 375 mg subcutaneously every 2 to 4 weeks</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Xol’</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Xolair which has no downstroke letters which gives the pair different shapes.</p> <p><u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted. There are no overlapping strengths or numerical similarity.</p> <p><u>Dose:</u> 1 tablet vs. xx mg</p> <p><u>Frequency:</u> Daily vs. every 2 to 4 weeks</p>
<p>Xifaxan (Rifaximin) Tablets, 200 mg, 550 mg</p> <p><u>Usual dose:</u> One tablet by mouth 2 to 3 times daily</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Xif’</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Xifaxan which has no downstroke letters which gives the pair different shapes. Xeljanz has an additional downstroke letter ‘l’ that is not present in Xifaxan.</p> <p><u>Strength:</u> Both are multiple strength products which must be indicated on the prescription and there are no overlapping strengths or numerical similarity.</p>

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg and 10 mg</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Zuplenz (Ondansetron) Soluble film, 4 mg, 8 mg</p> <p><u>Usual dose:</u> 4 mg to 8 mg three times a day</p>	<p><u>Orthographic:</u> Both have similar ending letter strings, ‘anz’ and ‘enz’</p> <p><u>Route:</u> Both are oral</p>	<p><u>Orthographic:</u> Xeljanz has an upstroke in the 3rd position and a downstroke in the 4th position vs. Zuplenz which has an upstroke in the 5th position and a downstroke in the 3rd position which gives the pair different shapes.</p> <p><u>Strength:</u> Both are multiple strength products which must be indicated on the prescription and there no overlapping strengths or numerical similarity.</p>
<p>Velban (Vinblastine Sulfate) Power for Injection, 1 mg/mL, 2 mg/mL</p> <p>*Discontinued but generics available</p> <p><u>Usual dose:</u> 1.4 mg/m² to 2 mg/m² intravenously once a week</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xel’ and ‘Vel’</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Velban which has no downstroke letters which give the pair different shapes.</p> <p><u>Dose:</u> 1 tablet vs. xx mg/m²</p> <p><u>Frequency:</u> daily vs. weekly</p> <p><u>Strength:</u> Both are multiple strength products which must be indicated on the prescription</p>
<p>Reyataz (Atazanavir Sulfate) Capsules, 100 mg, 150 mg, 200 mg, 300 mg</p> <p><u>Usual dose:</u> 100 to 400 mg by mouth once daily</p>	<p><u>Orthographic:</u> Both have similar ending letter strings, ‘nz’ and ‘az’</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p> <p><u>Frequency:</u> Both are daily</p>	<p><u>Orthographic:</u> Xeljanz has no cross-stroke letters vs. Reyataz which has a cross-stroke letter ‘t’ in the 5th position giving the pair different shapes. Also Xeljanz has an additional upstroke letter ‘l’ in the 3rd position.</p>

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg and 10 mg</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xalkori (Crizotinib) Capsules, 200 mg, 250 mg</p> <p><u>Usual dose:</u> 200 mg to 250 mg by mouth twice daily</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, 'Xel' and 'Xal'</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter 'j' in the 4th position vs. Xalkori which has no downstroke letters and ends in a dotted letter 'i' which give the pair different shapes.</p> <p><u>Strength:</u> Both are multiple strength products which must be indicated on the prescription and there no overlapping strengths or numerical similarity</p>
(b) (4)		
<p>Salagen (Pilocarpine Hydrochloride) Tablets, 5 mg, 7.5 mg</p> <p><u>Usual dose:</u> 10 mg to 30 mg per day in divided doses (2 to 3 times a day. In Sjogren syndrome the dose is 5 mg four times a day)</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, 'Xel' and 'Sal'</p> <p><u>Strength:</u> Both have an overlapping strength of 5 mg</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> There is a letter 'a' separating the upstroke 'l' and downstroke 'g' in Salagen vs. the upstroke and downstroke appear together in Xeljanz.</p>

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg and 10 mg</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Invanz (Ertapenem) Powder for Injection, 1 g</p> <p><u>Usual dose:</u> 1 g once daily administered intramuscularly or intravenously</p>	<p><u>Orthographic:</u> Both have the same ending letter strings ‘anz’</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Invanz which has no downstroke letters which give the pair a different shape when scripted. The beginning letter strings, ‘Xal’ vs. ‘Inv’ look different when scripted.</p> <p><u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted.</p> <p><u>Route:</u> Oral vs. Intramuscularly or intravenously which would need to be indicated on the prescription</p>
<p>Relenza (Zanamivir) Power for oral inhalation, 5 mg per blister</p> <p><u>Usual dose:</u> 10 mg to 20 mg per day for 5 to 28 days</p>	<p><u>Orthographic:</u> Both have the similar ending letter strings ‘anz’ and ‘nza’</p> <p><u>Strength:</u> Both have an overlapping strength of 5 mg</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Relenza which does not giving them different shapes. Also the ending letter strings ‘anz’ vs. ‘nza’ look different when scripted.</p>
<p>Xanax (Alprazolam) Tablets, 0.25 mg, 0.5 mg, 1 mg, 2 mg</p> <p><u>Usual dose:</u> 0.25 mg to 2 mg by mouth three times a day</p>	<p><u>Orthographic:</u> Both have similar beginning letter strings, ‘Xe’ and ‘Xa’</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter ‘j’ in the 4th position vs. Xanax which has no downstroke letters and an upstroke letter ‘l’ in the 3rd position which give the pair different shapes.</p>

<p>Proposed name: Xeljanz (Tofacitinib)</p> <p>Dosage Form(s): Tablet</p> <p>Strength(s): 5 mg and 10 mg</p> <p>Usual Dose: One tablet by mouth once daily</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Xenazine (Tetrabenazine) Tablets, 12.5 mg, 25 mg</p> <p><u>Usual dose:</u> 12.5 mg to 50 mg by mouth per day in divided doses</p>	<p><u>Orthographic:</u> Both have the same beginning letter strings, 'Xe'</p> <p><u>Dosage Form and Route:</u> Both are tablets and oral</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter 'j' in the 4th position vs. Xenazine which has no downstroke letters which give the pair different shapes.</p>
<p>Xenical (Orlistat) Capsules, 120 mg</p> <p><u>Usual dose:</u> One capsule by mouth three times a day</p>	<p><u>Orthographic:</u> Both have the same beginning letter strings, 'Xe'</p> <p><u>Route:</u> Both are oral</p>	<p><u>Orthographic:</u> Xeljanz has a downstroke letter 'j' in the 4th position vs. Xenical which has no downstroke letters and ends in an upstroke letter 'l' which give the pair different shapes.</p> <p><u>Strength:</u> Multiple strengths which must be indicated on the prescription vs. Single strength which may be omitted.</p>

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/s/

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**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date: January 20, 2011

Reviewer(s): Lissa C. Owens, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Carlos Mena-Grillasca, RPh
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): (b) (4) (Tofacitinib) Tablets
5 mg and 10 mg

Application Type/Number: NDA 203214

Applicant/Sponsor: Pfizer

OSE RCM #: 2011-4192

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