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

Memo for Proprietary Name-Otezla

Date:	January 29, 2014
Reviewer:	Teresa McMillan, PharmD Division of Medication Error Prevention and Analysis
Associate Director:	Lubna Merchant, PharmD, M.S. Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Otezla (Apremilast) Tablets 30 mg
Application Type/Number:	NDA 205437
Sponsor:	Celgene Corporation

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

DMEPA found the proposed name, Otezla, acceptable in OSE Review # 2013-789 dated June 20, 2013. In this review we indicated the proposed proprietary name must be re-reviewed prior to approval of the NDA. However, DMEPA no longer re-reviews proposed proprietary names within 90 days of the anticipated application approval, unless there is a change in the proposed product characteristics.

Since none of the proposed product characteristics were altered, our conclusion that the proposed proprietary name is acceptable has not changed since the aforementioned review. DMEPA has no objection to the proprietary name, Otezla, for this product at this time.

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

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

/s/

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01/30/2014

LUBNA A MERCHANT
01/30/2014

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:	6/20/13
Reviewer:	Teresa McMillan, PharmD Division of Medication Error Prevention & Analysis
Team Leader:	Lubna Merchant, M.S., PharmD Division of Medication Error Prevention & Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention & Analysis
Drug Name and Strength:	Otezla (Apremilast) Tablets 30 mg
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OSE RCM #:	2013-789

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Otezla, 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 New Drug Application is currently under review with the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP). In the Investigational New Drug phase of this submission, the first and second proposed proprietary names, [redacted] (b) (4) were found unacceptable by DMEPA in OSE Reviews #2011-4567 and #2011-4561 and #2012-1519 and #2012-1536, respectively.

On March 21, 2013, Celgene Corporation submitted a request to the Agency for an assessment of the proposed proprietary name under NDA 205437.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 27, 2013 proprietary name submission.

- Active Ingredient: Apremilast
- Indication of Use: Treatment of adult patients with active psoriatic arthritis.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 30 mg
- Dose and Frequency:

  Initial titration schedule as shown below in Table 1.

  Table 1. Dose Titration Schedule

Day 1	Day 2		Day 3		Day 4		Day 5		Day 6 & thereafter	
AM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
10 mg	10 mg	10 mg	10 mg	20 mg	20 mg	20 mg	20 mg	30 mg	30 mg	30 mg

  Maintenance dose- 30 mg twice daily.

- How Supplied: Tablets are supplied in the following strengths and package configurations:

Package configuration	Tablet strength	NDC code
Bottles of 60	30 mg	59572-630-06
Two week starter pack	13-tablet blister titration pack containing: 10 mg, 20 mg, and 30 mg tablets with an additional (14) 30 mg tablets	59572-630-27

- Storage: Store at room temperature, (b) (4)

2. RESULTS

The following sections provide the information obtained and considered in the overall 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 (DPARP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The May 2, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Otezla, was not derived from one particular concept. This 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.

2.2.3 FDA Name Simulation Studies

Seventy-one practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products that are under review. Nineteen participants interpreted the name correctly as "Otezla". The remaining participants provided incorrect responses. The remaining misinterpretations from all responses occurred with the letter 'O' being misinterpreted for the letters 'O', 'P', 'Q' and letter strings 'Au', 'Oc' , 'Op', 'Or', 'Ott', 'and Oxt', the letter 'e' for the letter 'a' and the letter strings 'ce', and the letter 'z' for the letters 's', 'g', and letter strings 'ss' and 'za'. We have considered these variations in our look-alike and sound-alike searches and analysis (see Appendix B). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 5, 2013 e-mail, the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B also lists additional possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Otezla. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Otezla identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Tables 1 also includes the names requiring further evaluation identified by (b) (4)

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and External Name Study)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Uloric	FDA	Alimta	FDA	Otozin	FDA
Oforta	FDA	Oleptro	FDA	Atripla	Both
Atelvia	FDA	Oxecta	FDA	Ulfesia	FDA
Adoxa	FDA	Alert	FDA	Ahist	FDA
Utex 10	FDA	(b) (4)	FDA	Obestin-30	FDA
Otedram	FDA	Otex HC	FDA	Otede	FDA
Otenol	FDA	PEGLA	FDA	Omezol	FDA
(b) (4)	FDA	Atozet***	FDA	(b) (4)	FDA
(b) (4)	FDA	Atreza	FDA	Qtest	FDA
Aliclen	FDA	Atridox	FDA	Atralin	FDA
Alocril	FDA	Allegra Allergy***	FDA	(b) (4)	FDA
Astepro	FDA	Qutenza	FDA	(b) (4)	FDA
(b) (4)	FDA	Oxilan	FDA	Ativan	FDA
Orencia	FDA	Alora	FDA	Glumetza	External
Oracea	FDA	Alinia	FDA	Onglyza	Both
Oxistat	FDA	Optivar	FDA	Dazidox	FDA
Atarax	External	Cytotec	External		
Dizac	FDA	(b) (4)	FDA		
Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Teslac	FDA	Zotex LAX	FDA	Omnaris	External
Zetia	External	Savella	External		
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Otezla	FDA	Ocella	Both	Apidra	Both

Our analysis of the 60 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 60 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Pulmonary, Allergy, and Rheumatology Products (DPARP) via e-mail on June 5, 2013. At that time we also requested additional information or concerns that could inform our review. The Division of Pulmonary, Allergy, and Rheumatology Products (DPARP), stated no additional concerns with the proposed proprietary name, Otezla.

3 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.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The results are subject to change. If any of the proposed product characteristics as stated in your submission are altered, the name must be resubmitted for review.

4 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.

20. ***Natural Standard (http://www.naturalstandard.com)***

    Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

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

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[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**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• 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	• 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	• 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 gather 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 posses 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

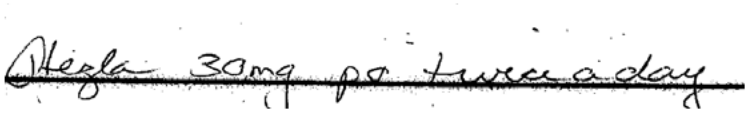
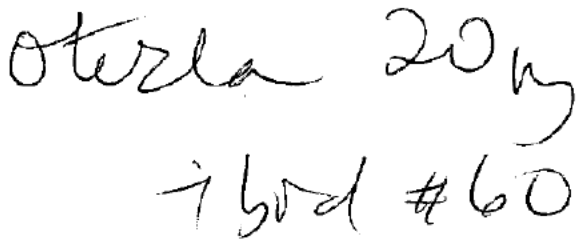
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Otezla	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'O'	Q, A, U, D, L, 0, P	'Oh'
lower case 'o'	a, u, l, c, e	'Oh'
lower case 't'	r, f, x, A	'd'
lower case 'e'	a, i, l, o, u, p	any vowel
lower case 'z'	c, e, g, n, m, q, r, s, v, y	c,s,x
lower case 'l'	b, e, s, p, i	
lower case 'a'	Any vowel,'el', 'ci', 'cl', 'd', 'c', 'n'	Any vowel
Letter strings in Name, Otezla	**Scripted May Appear as**	**Spoken May Be Interpreted as**
Ot		'Op', 'Au', 'Ott, 'Ox', 'Or', 'Oc"

Appendix C: Prescription Simulation Samples and Results

Figure 1. Otezla (Conducted on 04/05/2013)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Otezla 20 mg 1 bid #60
Outpatient Prescription: 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study
71 People Responded

Study Name: Otezla

Total	24	24	23
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
???	0	1	0	1
ATESLA	0	1	0	1
ATEZLA	0	4	2	6
AUTESLA	0	1	0	1
OCTASLA	0	1	0	1
OCTAZELA	0	1	0	1
OCTAZLA	0	3	0	3
OCTESLA	0	1	0	1
OCTEZLA	0	1	0	1
OPTEZLA	0	1	0	1
ORTEGLA	0	0	1	1
OTCESLA	0	1	0	1
OTEGLA	0	0	1	1
OTERLA	20	0	0	20
OTESLA	0	4	0	4
OTEZLA	4	1	14	19
OTTAZLA	0	1	0	1
OTTESSLA	0	1	0	1
OXTAZALA	0	1	0	1
PTEGLA	0	0	1	1
PTEZLA	0	0	3	3
QTEZLA	0	0	1	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 Otezla	Failure preventions
1	Alert	Caffeine	Look alike	Name identified in Clinical Pharmacology database. Unable to find product characteristics in commonly used drug databases.
2	Obestin-30	Phentermine Hydrochloride	Look alike	This product has been withdrawn per Federal Register effective on June 28, 1993. However, it is unclear if this product was withdrawn for safety reasons.
3	Otedram	Bromazepam	Look alike	The pair has sufficient orthographic differences. This is also an international product marketed in Mexico.
4	Otex HC	Ciprofloxacin and Hydrocortisone	Look alike	The pair has sufficient orthographic differences. This is also an international product marketed in Canada.
5	Otede	Diphendydramine	Look alike	The pair has sufficient orthographic differences. This is also an international product marketed in Indonesia.
6	Otenol	Terbinafine	Look alike	The pair has sufficient orthographic differences. This is also an international product marketed in Malaysia
7	Atozet***	Ezetimibe and Atorvastatin	Look alike	Proposed proprietary name found unacceptable by DMEPA (OSE#2012-2940). Product approved under new proprietary name Liptruzet.
8	(b) (4)		Look alike	(b) (4)
9			Look alike	
10	Qtest	N/A	Look alike	The pair has sufficient orthographic differences. In addition, this is a medical device and not a drug product.
11	Atridox	Doxycycline	Look alike	The pair has sufficient orthographic differences.
12	Atralin	Tretinoin	Look alike	The pair has sufficient orthographic differences.
13	Alocril	Nedocromil	Look alike	The pair has sufficient orthographic differences.
14	Allegra Allergy***	Fexofenadine HCL	Look alike	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2010-1058, 2010-1029, 2010-1060, 2010-1061). Product approved under new proprietary name Allegra.
15	(b) (4)		Look alike	(b) (4)

	Proprietary Name	Active Ingredient	Similarity to Otezla	Failure preventions
16	Astepro	Azelastine	Look alike	The pair has sufficient orthographic differences.
17	(b) (4)		Look alike	(b) (4)
18			Look alike	
19	Alora	Estradiol	Look alike	The pair has sufficient orthographic differences.
20	Ativan	Lorazepam	Look alike	The pair has sufficient orthographic differences.
21	Glumetza	Metformin	Look alike	The pair has sufficient orthographic differences.
22	Atarax	Hydroxyzine	Look alike	The pair has sufficient orthographic differences.
23	Cytotec	Misoprostol	Look alike	The pair has sufficient orthographic differences.
24	Dazidox	Oxycodone	Look alike	The pair has sufficient orthographic differences.
25	Optivar	Azelastine	Look alike	The pair has sufficient orthographic differences.
26	Oxistat	Oxiconazole	Look alike	The pair has sufficient orthographic differences.
27	Onglyza	Saxagliptin	Look alike	The pair has sufficient orthographic differences.
28	Dizac	Diazepam	Look alike	The pair has sufficient orthographic differences.
29	Teslac	Testolactone	Sound alike	The pair has sufficient and phonetic differences.
30	Zotex LAX	Dextromethorphan; Guaifenesin; Phenylephrine	Sound alike	The pair has sufficient orthographic differences.
31	Omnaris	Ciclesonide	Sound alike	The pair has sufficient orthographic differences.
32	Zetia	Ezetimibe	Sound alike	The pair has sufficient orthographic differences.
33	Savella	Milnacipran	Sound alike	The pair has sufficient orthographic differences.
34	(b) (4)		Look alike	(b) (4)
35			Look alike	

Proprietary Name		Active Ingredient	Similarity to Otezla	Failure preventions
36	Otozin	Benzocaine, Glycerol, Phenazone, Zinc Acetate	Look alike	Name identified in Micromedex database. Unable to find product characteristics in commonly used drug databases.
37	Oforta	Fludarabine Phosphate	Look alike	This product was withdrawn on March 29, 2013. It is unclear if it was withdrawn due to safety concerns. In addition, there are no generic equivalents
38	Utex 10	Urea	Look alike	Name identified in Redbook database. Unable to find product characteristics in commonly used drug databases.
39	Omezol	Omeprazole	Look alike	The pair has sufficient orthographic differences. This is also an international product marketed in several countries.
40	(b) (4)		Sound alike	(b) (4)
41	Otezla	Apremilast	Look and sound alike	This name is the subject of this review.

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.

Proposed name: Otezla (Apremilast) **Dosage form(s): Oral Tablet** **Strength(s): 30 mg** *****10 mg and 20 mg in titration pack only** **Usual dose: 1 tablet twice daily** ******Psoriatic arthritis: 20 and/or 30 mg twice daily** ******The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
1	Uloric (Febuxostat) <u>Oral Tablets</u> 40 mg, 80 mg <u>Usual Dose</u> 40 or 80 mg once daily.	*<u>Similarities</u>* <u>Orthographics</u> The letter string 'Ul' when scripted appears similar to the letter string 'Ot'. The letter string 'ric' when scripted appears similar to the letter string 'zla'.	*<u>Differences</u>* <u>Orthographics</u> The letter string 'oric' when scripted appears different than the letter string 'ezla'. <u>Strength</u> 20 mg, 30 mg vs. 40mg, 80 mg

Proposed name: Otezla (Apremilast) **Dosage form(s): Oral Tablet** **Strength(s): 30 mg** *****10 mg and 20 mg in titration pack only** **Usual dose: 1 tablet twice daily** *****Psoriatic arthritis: 20 and/or 30 mg twice daily** ******The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
2	Alimta (Pemetrexed) <u>Powder for Injection</u> 100 mg, 500 mg <u>Usual Dose</u> 500 -600 mg/m2 intravenously over 10 minutes once every 21 days	*<u>Similarities</u>* <u>Orthographics</u> Both names contain three upstrokes (A, l, t vs. O, t, l) in similar positions. The letter string 'Ali' when scripted appears similar to the letter string 'Ote'. The letter string 'mta' when scripted appears similar to the letter string 'zla'.	*<u>Differences</u>* <u>Strength</u> 20 mg, 30 mg vs. 100 mg, 500 mg <u>Usual Dose</u> 500 mg-600 mg2 vs. 1 tablet or 20 mg or 30 mg <u>Frequency of Administration</u> once every 21 days vs. twice daily

Proposed name: Otezla (Apremilast) **Dosage form(s): Oral Tablet** **Strength(s): 30 mg** *****10 mg and 20 mg in titration pack only** **Usual dose: 1 tablet twice daily** *****Psoriatic arthritis: 20 and/or 30 mg twice daily** ******The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
3	Oleptro (Trazodone) Extended-Release Tablet 150 mg, 300 mg Usual Dose 150 mg-375 mg once daily at bedtime.	*Similarities* Orthographics The letter string 'Ole' when scripted appears similar to the letter string 'Ote'. Strength and Usual Dose (similarity) 300 mg vs. 30 mg	*Differences* Orthographics The suffix 'ptro' when scripted appears different than the suffix 'zla'. Additionally, our prescription simulation study results did not demonstrate any confusion and misinterpretations between the letters 'z' and 'p'.

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
4	Atripla (Efavirenz; Emtricitabine; Tenofovir) <u>Oral Tablets</u> 600 mg;200mg,300mg <u>Usual Dose</u> Take one tablet once at bedtime	*<u>Similarities</u>* <u>Orthographics</u> The letter string 'Atr' when scripted appears similar to the letter string 'Ote'. <u>Usual Dose</u> One tablet	*<u>Differences</u>* <u>Orthographics</u> The letter strings 'ip' that appear in the middle of the name Atripla, looks different due to the loop in the "p" and the additional letter 'i' before it than the letter 'z' that appears in the middle of the name Otezla. Additionally, our prescription simulation study results did not demonstrate any confusion and misinterpretations between the letters 'z' and 'p'.

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
5	Atelvia (Risederonate) <u>Delayed-Release Tablet</u> 35 mg <u>Usual Dose</u> 35 mg once weekly taken after breakfast	*<u>Similarities</u>* <u>Orthographics</u> The letter string 'Ate' when scripted appears similar to the letter string 'Ote'. The letter string 'lv' when scripted appears similar to the letter string 'la'.	*<u>Differences</u>* <u>Orthographics</u> The upstroke letter 'l' is in the fourth position in the name Atelvia and the upstroke letter 'l' is in the 5th position in the name Otezla. Additionally, there are three letters following the upstroke letter 'l' in the name Atelvia and only one letter following the upstroke letter 'l' in the name Otezla. <u>Frequency of Administration</u> Once weekly vs. Twice daily

Proposed name: Otezla (Apremilast) **Dosage form(s): Oral Tablet** **Strength(s): 30 mg** *****10 mg and 20 mg in titration pack only** **Usual dose: 1 tablet twice daily** *****Psoriatic arthritis: 20 and/or 30 mg twice daily** ******The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
6	Oxecta (Oxycodone) Oral Tablet 5 mg, 7.5 mg Usual Dose 5-15 mg q4-6 hours prn	*Similarities* Orthographics The letter string 'Oxe' when scripted appears similar to the letter string 'Ote'. The letter string 'cta' when scripted appears similar to the letter string 'zla'. Usual Dose (achievable) 5 mg, 10 mg, 20 mg, 30 mg	*Differences* Frequency of Administration 4-6 hours prn vs. twice daily Strength Although there is an overlap in the 10 mg dose it will not be written as a dose alone because it is part of a titration package.

	Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
7	Ulesfia (Benzyl Alcohol) <u>Topical Lotion</u> 5% <u>Usual Dose</u> Use as Directed or Apply 4—48 ounces (depending on length of hair) of lotion to dry hair to completely saturate the scalp and hair; leave on for 10 minutes, then thoroughly rinse off with water. Repeat after 7 days.	*<u>Similarities</u>* <u>Orthographics</u> The letter string 'Ules' when scripted appears similar to the letter string 'Otez'. The letter string 'fia' when scripted appears similar to the letter string 'la'.	*<u>Differences</u>* <u>Usual Dose</u> Use as directed or Apply 4-48 ounces vs. 1 tablet or 20 mg, 30 mg <u>Frequency of Administration</u> once vs. twice daily

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
8	PEGLA-synonym for Pegaspargase <u>Solution for Injection</u> 3750 IU/mL <u>Usual Dose</u> 2500 IU/m^2 intravenously or intramuscularly once every 14 days	*<u>Similarities</u>* <u>Orthographics</u> The letter 'P' when scripted appears similar to the letter 'O'. The letter string 'egla' when scripted appears similar to the letter string 'ezla'.	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains an additional upstroke ('1') giving the names different shapes when scripted. <u>Usual Dose</u> 2500 IU/m2 vs. 1 tablet or 20 mg, 30 mg <u>Frequency of Administration</u> once vs. twice daily

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
9	Atreza (Atropine) <u>Oral Tablet</u> 0.4 mg <u>Usual Dose</u> 2 mg 30-60 minutes prior to anesthesia.	*<u>Similarities</u>* <u>Orthographics</u> The letter string 'Atrez' when scripted appears similar to the letter string 'Otez'. <u>Usual Dose</u> 2 mg vs. 20 mg	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains an additional upstroke ('1') giving the names different shapes when scripted. <u>Frequency of Administration</u> once vs. twice daily

	Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
10	Qutenza (Capsaicin) <u>Topical Patch</u> 8% <u>Usual Dose</u> Use up to 4 patches per application; patches should be applied for 60 minutes and repeated no more frequently than every 3 months as needed	*<u>Similarities</u>* <u>Orthographics</u> The letter 'Q' when scripted appears similar to the letter 'O'. The letter string 'tenz' when scripted appears similar to the letter 'tez'	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains an additional upstroke ('1') giving the names different shapes when scripted. Also the letter 'u' before the upstroke't' in the name Qutenza makes this name appear longer when scripted. <u>Usual Dose</u> 1-4 patches vs. 1 tablet or 20 mg, 30 mg <u>Frequency of Administration</u> once every 3 months vs. twice daily

	Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
11	Orencia (abatacept) <u>Powder for Injection</u> 250 mg <u>Solution for Injection</u> 125 mg/mL <u>Usual Dose</u> 125 mg subcutaneously once weekly or 500 mg-1000 mg intravenously once monthly	*<u>Similarities</u>* <u>Orthographics</u> Both names begin with the letter 'O'. The infix 'en' when scripted appears similar to the infix 'ez'.	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains two additional upstrokes ('t', '1') giving the names different shapes when scripted. <u>Strength</u> 125 mg, 250 mg vs. 20 mg, 30 mg <u>Usual Dose</u> 125 mg, or 500 mg-100 mg vs. 1 tablet or 20 mg, 30 mg <u>Frequency of Administration</u> once weekly or once monthly vs. twice daily

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s):, 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
12	Oracea (doxycycline) <u>Capsules</u> 40 mg <u>Usual Dose</u> One capsule once daily in the morning on an empty stomach, preferably at least one hour prior to or two hours after meals	*<u>Similarities</u>* <u>Orthographics</u> Both names begin with the letter 'O'. The infix 'ac' when scripted appears similar to the infix 'ez' <u>Dose (achievable)</u> 40 mg	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains two additional upstrokes ('t', '1') giving the names different shapes when scripted.

Proposed name: Otezla (Apremilast) **Dosage form(s): Oral Tablet** **Strength(s):, 30 mg** *****10 mg and 20 mg in titration pack only** **Usual dose: 1 tablet twice daily** *****Psoriatic arthritis: 20 and/or 30 mg twice daily** ******The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**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**
13	Ocella (Drospirenone; ethinyl estradiol) l&S <u>Oral Tablets</u> 3 mg;0.03 mg <u>Usual Dose</u> Take 1 tablet once daily	*<u>Similarities</u>* <u>Orthographics</u> Both names begin with the letter 'O' and end with the letter string 'la'. <u>Phonetics</u> Both names have three syllables and end with the 'la' sound. The letter 'O' sounds similar to the letter 'A' when enunciated.	*<u>Differences</u>* <u>Orthographics</u> The position of the two upstrokes ('l', 'l') in the name Ocella gives the names different shapes when scripted. <u>Phonetics</u> The infix 'cel' sounds distinctly different from the infix 'tez' when enunciated.

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s):30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
14	Apidra (insulin glulisine) L&S <u>Solution for Injection</u> 100 units/mL <u>Usual Dose</u> 10 units, 20 units, or 30 units subcutaneously 15 minutes before a meal or within 20 minutes after starting a meal.	*<u>Similarities</u>* <u>Orthographics</u> The letter 'A' when scripted appears similar to the letter 'O'. <u>Usual Dose (similarity)</u> 20 units, 30 units vs. 20 mg 30 mg <u>Phonetics</u> Both names have three syllables and end with the 'a' sound. The letter 'O' sounds similar to the letter 'A' when enunciated.	*<u>Differences</u>* <u>Orthographics</u> The position of the downstroke ('p') in the name Apidra gives the names different shapes when scripted. <u>Frequency of Administration</u> 15 minutes before a meal or within 20 minutes after starting a meal vs. twice daily <u>Phonetics</u> The infix 'pidr' sounds distinctly different from the infix 'tezl' when enunciated.

	Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
15	Adoxa (doxycycline) <u>Oral Capsule</u> 150 mg <u>Oral Tablet</u> 50 mg, 75 mg, 100 mg <u>Usual Dose</u> 50-150 mg twice daily	*<u>Similarities</u>* <u>Orthographics</u> The letter 'A' when scripted appears similar to the letter 'O'. Both names end with the letter 'a'. <u>Usual Dose (acheivable)</u> 50 mg <u>Frequency of Administration</u> Twice daily	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains one additional upstroke ('1') giving the names different shapes when scripted.

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
16	Ahist (Chlorpheniramine) <u>Extended-Release Tablet</u> 12 mg <u>Usual Dose</u> 12 to 18 mg (1 to 1.5 tablets) twice daily; not to exceed 36 mg in 24 hours	*<u>Similarities</u>* <u>Orthographics</u> The letter 'A' when scripted appears similar to the letter 'O'. Both names contain 3 upstokes ('A', 'h', 't' vs. 'O', 't', 'l') in similar positions. <u>Usual Dose</u> 1 tablet <u>Frequency of Administration</u> Twice daily	*<u>Differences</u>* <u>Orthographics</u> The letter 'a' at the end of the name Otezla gives the names slightly different shapes and elongates the name when scripted.

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
17	Aliclen (salicylic acid) <u>Topical Shampoo</u> 6% <u>Usual Dose</u> Use as directed or Apply to affected area at night; place under occlusion and wash off in the morning.	*<u>Similarities</u>* <u>Orthographics</u> The letter 'A' when scripted appears similar to the letter 'O'. Both names contain 3 upstokes ('A', '1', 'l' vs. 'O', 't', 'l') in similar positions.	*<u>Differences</u>* <u>Orthographics</u> The letter 'n' at the end of the name Aliclen elongates the name when scripted. <u>Usual Dose</u> Use as directed or Apply to affected area vs. 1 tablet

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
18	Oxilan (ioxilan) <u>Solution for Injection</u> 300 mg/mL, 350 mg/mL <u>Usual Dose</u> 2 mL -250 mL once	*<u>Similarities</u>* <u>Orthographics</u> Both names begin with the letter 'O' and contain the letter string 'la' in similar positions. <u>Usual Dose</u> 2 ml, 3 mL, 20 mL, 30 mL vs. 20 mg, 30 mg	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains one additional upstroke ('1') giving the names different shapes when scripted. <u>Frequency of Administration</u> once vs. twice daily

Proposed name: Otezla (Apremilast) Dosage form(s): Oral Tablet Strength(s): 30 mg ***10 mg and 20 mg in titration pack only Usual dose: 1 tablet twice daily ***Psoriatic arthritis: 20 and/or 30 mg twice daily ****The Applicant is only proposing the 30 mg to be marketed. However if the Agency decides if 20 mg twice daily is acceptable then the 20 mg will be marketed.		Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	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
19	Alinia (Nitazoxanide) <u>Oral Tablet</u> 500 mg <u>Powder for Oral Suspension</u> 100 mg/5mL <u>Usual Dose</u> 100 mg-500 mg twice daily	*<u>Similarities</u>* <u>Orthographics</u> The letter 'A' when scripted appears similar to the letter 'O'. <u>Usual Dose</u> 200 mg , 300 mg vs. 20 mg, 30 mg <u>Frequency of Administration</u> Twice dail	*<u>Differences</u>* <u>Orthographics</u> The name Otezla contains one additional upstroke ('1') giving the names different shapes when scripted.

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/s/

LUBNA A MERCHANT
06/20/2013

CAROL A HOLQUIST
06/20/2013