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

Date:	January 16, 2013
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Tecfidera (Dimethyl Fumarate) Delayed-release Capsules 120 mg and 240 mg
Application Type/Number:	NDA 204063
Applicant/Sponsor:	Biogen Idec
OSE RCM #:	2012-2508

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

CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Tecfidera, 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

Dimethyl fumarate is a New Molecular Entity (NME). This product was reviewed under IND 073061 with the proposed proprietary name, (b) (4), which was found acceptable in OSE Review # 2009-2403 dated April 28, 2010. The Applicant subsequently requested to withdraw the name, (b) (4) and requested review of the proposed proprietary name, (b) (4) In OSE Review # 2010-2674 dated May 26, 2011, the Division of Medication Error Prevention and Analysis (DMEPA) found the name unacceptable (b) (4) . On February 29, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) under NDA 204063. In OSE Review # 2012-542 dated May 23, 2012, DMEPA found the name unacceptabl (b) (4) On May 30, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) In OSE Review # 2012-1263, DMEPA found the name unacceptable (b) (4) On August 29, 2012, the Applicant submitted a request for the review of the proposed proprietary name, (b) (4) On October 19, 2012, the OSE Project Manager e-mailed the Applicant stating that DMEPA identified a foreign produc (b) (4) On October 24, 2012, the Applicant withdrew the proposed proprietary name (b) (4)

On October 24, 2012, the Applicant submitted a request for the review of the proposed proprietary name, Tecfidera.

The labels and labeling for Dimethyl Fumarate were reviewed under separate cover (OSE Review # 2012-530).

1.2 PRODUCT INFORMATION

The following product information is provided in the October 24, 2012 proprietary name submission.

- Active Ingredient: Dimethyl Fumarate
- Indication of Use: Treatment of patients with relapsing multiple sclerosis (b) (4)

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- Route of Administration: Oral
- Dosage Form: Delayed-release capsules
- Strength: 120 mg, 240 mg
- Dose and Frequency: 120 mg by mouth twice daily for 7 days, then 240 mg by mouth twice daily; temporary dose reduction to 120 mg twice daily may reduce occurrence of flushing and GI side effects – within 1 month, the recommended dose of 240 mg twice daily should be resumed
- How Supplied:
  - (b) (4)
  - 30 day starter pack (14-count bottle 120 mg capsules and 46-count bottle 240 mg capsules packaged in the same carton): retail and professional sample
  - 120 mg capsules
    - 14-count bottle: retail and professional sample
  - 240 mg capsules
    - 14-count bottle: retail and professional sample
    - 60-count bottle: retail
- Storage: Store at 15°C to 30 °C (59°F to 86 °F). Protect capsules from light; Once opened, discard bottles after 90 days
- Container and Closure Systems: HDPE bottles sealed with an aluminum foil induction seal and white polypropylene (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 Neurology Products (DNP) 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 November 28, 2012 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, Tecfidera, has no derivation or intended meaning. 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. Since Tecfidera is a delayed-release capsule, we evaluated whether or not the proposed name requires a modifier to signal the delayed-release nature of the product (see Failure Mode and Effects Analysis of Modifier – Section 2.2.6).

2.2.3 FDA Name Simulation Studies

Eighty-four practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products, but the verbal prescription interpretation "Taxadera" sounds similar to "Taxotere," which was identified during the Expert Panel Discussion (EPD) as an orthographically similar name to Tecfidera. Due to similarity in speech, Taxotere was evaluated as an orthographically similar and phonetically similar name to Tecfidera in Appendix E. A comment was received from one of the participants that the written prescription reminded her of Terbinafine 250 mg. Terbinafine was evaluated as an orthographically similar name to Tecfidera in Appendix E. The written prescription studies show that the first letter 'T' can be misinterpreted as a 'J,' 'F,' or 'L.' The verbal prescription studies show that the infix 'cf' can be misheard as an 'x.' These written and verbal misinterpretations of letters and syllables of the name, Tecfidera, were evaluated. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, November 27, 2012 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 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, Tecfidera. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Tecfidera, identified by the Primary Reviewer (PR) and the Expert Panel Discussion (EPD). Table 1 also includes the name, Terbinafine, which was identified from a comment in the FDA Name Simulation Study that was not identified by DMEPA and required further evaluation.

Table 1: Collective List of Potentially Similar Names (PR, EPD, FDA)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Benefiber	EPD	Faslodex	EPD	Taclonex	EPD

Table 1: Collective List of Potentially Similar Names (PR, EPD, FDA)					
Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Decitabine	EPD	Jentadueto	EPD	Lofibra	EPD
Famotidine	EPD	Lidoderm	EPD	Actidose with Sorbitol and Actidose-Aqua	PR
Taladine	EPD	Trabedersen	PR	Terbinafine	FDA
Teflaro	EPD	Tekturna	EPD	Terfenadine	EPD
Lubriderm	PR	Ticlodipine	EPD	Barbidonna	PR
Lobeline	EPD	Zorbtive	EPD	Fastlene	EPD
Istodax	EPD	Rebif Rebidose***	PR	Zaditor	EPD
Bifidus	PR	Lidodan	EPD	Trifedrine	PR
Lactulose	EPD	Lubrifair	EPD	Tibolone	EPD
Testosterone	EPD	Profiderall	PR	Zoladex	EPD
Testoderm	EPD	TechneScan and TechneScan MDP	EPD	(b) (4)	PR
Tirofiban	EPD				
Look and Sound Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Taxotere	EPD				

Our analysis of the 38 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 38 names do not pose a risk for confusion as described in Appendices D through E.

2.2.6 Failure Mode and Effects Analysis of Modifier

As proposed, the Applicant does not include a modifier with the name (e.g., EC, En-tabs) to convey that Tecfidera is a delayed-release dosage form. Tecfidera is a new molecular entity in which there is no immediate-release dosage form available.

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We evaluated whether the lack of modifier raises a potential safety concern, specifically if practitioners or patients were to assume that Tecfidera is an immediate-release dosage form because no modifier is present in the proprietary name to signal the delayed-release nature of the product. Therefore, we evaluated errors associated with currently marketed products to consider whether a modifier may be appropriate for this drug to convey the delayed-release properties of this product.

First, we identified delayed-release products approved without a modifier in the proprietary name and reviewed documented errors relating to wrong technique. Wrong technique errors involved patients or practitioners, chewing, splitting, opening, or crushing the delayed-release oral dosage forms when these products were intended to be administered intact. Wrong technique errors occurred despite the presence of clear labeling directives to administer the products intact.

We then considered whether the lack of a modifier may actually contribute to practitioners' and patients' knowledge deficit about the delayed-release properties of the drug product. As it relates to this product, this consideration led us to evaluate whether the addition of a modifier to the Tecfidera name might help to avoid some of the wrong technique errors.

We reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms That Should Not Be Crushed" to identify if a modifier exists that could possibly convey that a delayed-release dosage form cannot be manipulated or that conveys the frequency of administration associated with a delayed-release dosage form. We focused our review on those names with modifiers for delayed-release products (e.g. EC, En-tabs), since the Institute of Medicine has charged FDA and Industry to standardize abbreviations to the greatest extent possible. Our review found that this list contains a majority of proprietary names without a modifier (n = 17) versus proprietary names with a modifier (n = 3). Based on this information, we conclude that there is no standard single modifier currently on the market today that is definitively linked to the requirement that a delayed-release product should not be manipulated prior to administration. Additionally, the frequency of administration for currently marketed delayed-release dosage forms vary from once daily to four times daily to once weekly. Based on this information, there is insufficient evidence to conclude that a modifier can convey the delayed-release properties of a product to prevent wrong technique errors or wrong frequency of administration errors. Additionally, there is also no currently marketed immediate-release dosage form of this product that the proposed product would need to distinguish itself from.

Given the totality of the factors considered above, there is no compelling evidence to support the necessity to request a modifier for the proposed proprietary name, Tecfidera, at this time. If approved, DMEPA will monitor for medication errors where the proprietary name is a contributing factor to the error.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on December 26, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DNP on

December 26, 2012, a reviewer stated that the proposed proprietary name Tecfidera looked similar to the name, Terfenadine. The name Terfenadine was also identified by EPD and was evaluated in Appendix E and found not to pose a risk for confusion.

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 Laurie Kelley, OSE project manager, at 301-796-5068.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Tecfidera, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 24, 2012 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 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.

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

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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Tecfidera	Scripted May Appear as	Spoken May Be Interpreted as
T	F, J, I, Z, L	D
t	x, A, l	d
e	a, i, l, o, u	a, i, o, u
c	a, e, i, l, r	k, x, xt
ec	u	
f	t, b	pf, ph
i	e, l, r	e
d	cl, a, ci	b, t, g
e	a, i, l, o, u, r	a, i, o, u
r	s, n, e, v, c, i	
er	u, v, n	
a	ce, ci, cl, d, el, o, u, n	e, i, o, u

Appendix C: Prescription Simulation Samples and Results

Figure 1. Study (Conducted on November 2, 2012)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Tecfidera 120mg po twice daily	Tecfidera 240 mg 1 po bid # 60
Outpatient Prescription: Tecfidera 240 mg 1 po BID #60	

Study Name: Tecfidera

As of Date 11/21/2012

194 People Received Study

84 People Responded

Study Name: Tecfidera

Total	28	25	31	
INTERPRETATION	**INPATIENT**	**VOICE**	**OUTPATIENT**	**TOTAL**
?	0	0	1	1
FECFIDERA	0	0	5	5
FEFIDERA	0	0	1	1
FERFIDERA	0	0	1	1
JECFRIDOVA	1	0	0	1
LECFIDERA	1	0	0	1
TAXADERA	0	1	0	1
TECBIDOVOR	1	0	0	1
TECFIDEN	0	0	2	2
TECFIDERA	2	0	19	21
TECFIDERON	3	0	0	3
TECFIDEVOR	1	0	0	1
TECFIDOVA	1	0	0	1
TECFIDRON	1	0	0	1
TECFRARON	1	0	0	1
TECFRAVA	1	0	0	1
TECFRIDERA	2	0	0	2
TECFRIDERAN	1	0	0	1
TECFRIDERON	7	0	0	7

TECFRIDORA	1	0	0	1
TECFRIDORON	1	0	0	1
TECFRIDOVOR	1	0	0	1
TECFROLERA	1	0	0	1
TECRDERON	1	0	0	1
TERFIDERA	0	0	1	1
TERFIDERA 240MG	0	0	1	1
TEXADARA	0	2	0	2
TEXADERA	0	14	0	14
TEXAGARA	0	1	0	1
TEXAGERA	0	2	0	2
TEXIDERA	0	2	0	2
TEXODARA	0	1	0	1
TEXTADERA	0	1	0	1
TEXTAGAB	0	1	0	1

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

No.	Proprietary Name	Active Ingredient	Similarity to Tecfidera	Failure preventions
1.	Jentadueto	Linagliptin and Metformin	Look alike	The pair has sufficient orthographic differences.
2.	Tekturna	Alskiren	Look alike	The pair has sufficient orthographic differences.
3.	Testosterone		Look alike	The pair has sufficient orthographic differences.
4.	Taclonex	Calcipotriene and Betamethasone Dipropionate	Look alike	The pair has sufficient orthographic differences.
5.	TechneScan and TechneScan MDP	Technetium TC-99 M Kit	Look alike	The pair has sufficient orthographic differences.
6.	Istodax	Romidepsin	Look alike	The pair has sufficient orthographic differences.
7.	Trifedrine	Chlorpheniramine and Phenylpropanolamine	Look alike	Phenylpropanolamine containing products were discontinued in the US by the FDA due to safety reasons.
8.	Tibolone		Look alike	NDA application found not approvable by the FDA in 2006.
9.	Lobeline		Look alike	(b) (4) [redacted]
10.	Lidodan	Lidocaine	Look alike	International product marketed in Canada
11.	Trabedersen		Look alike	Orphan drug. No pending application within the agency.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Benefiber (Wheat dextrin) Powder, Chewable Tablets, Caplets, Stick Packs <u>Dosage:</u> Powder – One to two teaspoonfuls by mouth three times daily Chewable Tablets – One and one half tablets to three tablets by mouth up to three times daily Caplets – Three caplets by mouth up to three times daily Stick Packs – Stir one packet into 4 ounces to 8 ounces of beverage until dissolved	<u>Orthographic:</u> The first letter 'b' and 't' can look similar when scripted. Both names contain the letter 'e' at the second position and contain the letter pair 'fi' in the infix followed by another upstroke letter. Both names also contain the letter pair 'er' following the second upstroke letter. Route of Administration: Both administered orally	<u>Orthographic:</u> The prefix 'bene' in Benefiber appears longer than the prefix 'tec' in Tecfidera when scripted. <u>Strength:</u> Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. <u>Dosage:</u> Tecfidera is available in a starter pack in which it may be prescribed as 'use as directed'. Although both products may be prescribed as 'use as directed', the prescription for Tecfidera would need to indicate "starter pack" and may minimize the risk of confusion between the names.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Decitabine Solution for Injection Strength: 50 mg Dosage: 15 mg/m^2 intravenously every 8 hours for 3 days, repeated every 6 weeks; 20 mg/m^2/day intravenously on days 1 to 5, repeated every 4 weeks	Orthographic: Both names contain the letter pair 'ec' at the second and third position. Both names contain a cross stroke letter and an upstroke letter in the infix. The letter string 'ine' in Decitabine and the letter string 'era' in Tecfidera look similar when scripted. Dosage: There is numerical similarity between Decitabine 24 mg (15 mg/m^2 dose with a body surface area of 1.6 m^2) and Tecfidera 240 mg	Orthographic: The first letter 'T' and 'D' look different when scripted. Decitabine contains the extra letter 'i' at the fourth position. The letter pair 'ab' in Decitabine and the letter pair 'id' look different when scripted.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Famotidine Tablets, Powder for Suspension, Solution for Injection Strength: 10 mg, 20 mg, 40 mg Tablets; 40 mg per 5 mL Powder for Suspension; 10 mg per mL, 200 mg per 20 mL, 20 mg per 2 mL, 20 mg per 50 mL, 40 mg per 4 mL Solution for Injection Dosage: 10 mg by mouth once or twice daily; 20 mg by mouth or intravenously once or twice daily; 40 mg by mouth or intravenously once or twice daily; 20 mg to 160 mg by mouth or intravenously every 6 hours	Orthographic: The first two letter 'Fa' and 'Te' look similar when scripted. Both names contain a cross stroke letter and an upstroke letter in the infix. The letter string 'ine' in Famotidine and the letter string 'era' in Tecfidera look similar when scripted. Dosage: Both products can be prescribed with a dosage of 120 mg Route of administration: Both products can be administered orally. Frequency of administration: Both products can be administered twice daily	Orthographic: The letter pair 'mo' in Famotidine and the letter 'c' in Tecfidera look different when scripted. The letter pair 'mo' lengthens the prefix in Famotidine compared to Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Teflaro (Ceftaroline Fosamil) Powder for Injection Strength: 400 mg, 600 mg Dosage: 200 mg, 300 mg, 400 mg, or 600 mg intravenously every 12 hours	Orthographic: Both names begin with the letters 'Te' and contain a cross stroke letter 'f' and an upstroke letter in the infix. The letter string 'aro' in Teflaro and the letter string 'era' in Tecfidera look similar when scripted. Frequency of administration: Both products are administered twice daily.	Orthographic: The prefix 'Tec' in Tecfidera contains an extra rounded letter 'c' giving it a longer appearance than the prefix 'Te' in Teflaro. The infix 'fid' in Tecfidera appears longer when scripted than the infix 'fl' in Teflaro. Strength and dosage: The strengths and dosages of Teflaro and Tecfidera do not overlap. The 600 mg strength of Teflaro can be achieved with five capsules of Tecfidera 120 mg; however, a dosage of Tecfidera 600 mg is outside of the usual dosage range.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Testoderm (Testosterone) Transdermal System <u>Strength:</u> 4 mg/24 hours <u>Dosage:</u> Apply one patch to the scrotal area 22 hours out of 24 hour period Testoderm has been discontinued, but Androderm is still available.	<u>Orthographic:</u> Both names begin with the letters 'Te' and contain a cross stroke letter at the fourth position. Both names also contain the letter string 'der' starting at the sixth position. <u>Dosage:</u> Both products may be prescribed as 'Use as directed.'	<u>Orthographic:</u> The letter string 'sto' in Testoderm and the letter string 'cfi' in Tecfidera look different when scripted. <u>Strength:</u> Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Testoderm does not overlap with the strengths of Tecfidera. <u>Dosage:</u> Tecfidera is available in a starter pack in which it may be prescribed as 'use as directed'. Although both products may be prescribed as 'use as directed', the prescription for Tecfidera would need to indicate "starter pack" and may minimize the risk of confusion between the names.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Zoladex (Gosrelin Acetate) Implant Strength: 3.6 mg, 10.8 mg Dosage: 3.6 mg subcutaneously every 28 days; 10.8 mg subcutaneously every 12 weeks	Orthographic: The first letter 'zo' and 'te' look similar when scripted. Both names contain two upstroke letters in the infix.	Orthographic: The letter pair 'la' in Zoladex and the letter string 'fi' in Tecfidera look different when scripted. The letter 'x' in Zoladex and the letter pair 'ra' in Tecfidera look different when scripted. Dosage: There is numerical similarity between Zoladex 3.6 mg and Tecfidera 360 mg (three capsules of 120 mg); however, a dosage of Tecfidera 360 mg is outside of the usual dosage range. Frequency of administration: Zoladex is administered every 28 days or every 12 weeks vs. Tecfidera is administered twice daily.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Lactulose Solution Strength: 10 grams per 15 mL Dosage: 30 mL to 45 mL (20 g to 30 g) by mouth three to four times daily; hourly doses of 30 mL to 45 mL by mouth may be given until a laxative effect is induced; 15 mL to 30 mL by mouth once daily; 300 mL lactulose rectally every 4 to 6 hours as needed	Orthographic: The first prefix 'Lac' and 'Tec' look similar when scripted. Both names contain a cross stroke letter at the fourth position and an upstroke letter at the sixth position. The letter string 'ose' in Lactulose and the letter string 'era' in Tecfidera look similar when scripted.	Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Lactulose does not overlap with the strengths of Tecfidera. Dosage: Tecfidera is available in a starter pack in which it may be prescribed as 'use as directed'. Although both products may be prescribed as 'use as directed', the prescription for Tecfidera would need to indicate "starter pack" and may minimize the risk of confusion between the names. In addition, if written, the dosage of Lactulose does not overlap with the dosage of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Fastlene (Caffeine) Capsules <u>Strength:</u> 200 mg <u>Dosage:</u> One capsule by mouth every 3 to 4 hours as needed	<u>Orthographic:</u> The first two letters 'Fa' and 'Te' look similar when scripted. Both names contain a cross stroke letter at the fourth position and another upstroke letter in the infix. The letter pair 'ene' in Fastlene and the letter pair 'era' in Tecfidera look similar when scripted. <u>Dosage, dosage form, and route of administration:</u> Both products can be prescribed as 'One capsule by mouth.'	<u>Orthographic:</u> The letter string 'stl' in Fastlene and the letter string 'cfid' in Tecfidera look different when scripted. <u>Strength:</u> Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Fastlene does not overlap with the strengths of Tecfidera. <u>Frequency of administration:</u> Fastlene is administered every 3 to 4 hours as needed vs. Tecfidera is administered twice daily.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Faslodex (Fulvestrant) Solution for Injection Strength: 50 mg per mL Dosage: 500 mg intramuscularly as two 5 mL injections, one in each buttock on days 1, 15, 20, and once monthly	Orthographic: The first two letters 'Fa' and 'Te' look similar when scripted. Both names contain an upstroke letter at the fourth position and contain the letter pair 'de' starting at the sixth position.	Orthographic: The letter string 'slo' in Faslodex and the letter string 'cfi' in Tecfidera look different when scripted. The letter 'x' in Faslodex and the letter pair 'ra' in Tecfidera look different when scripted. Strength and dosage: The strengths and dosages of Faslodex and Tecfidera do not overlap and are not achievable. Frequency of administration: Faslodex is administered on certain days and once monthly vs. Tecfidera is administered twice daily.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Lidoderm (Lidocaine) Transdermal System Strength: 5% Dosage: Apply up to 3 patches up to 12 hours in a 24 hour period	Orthographic: The first two letters 'Li' and 'Te' look similar when scripted. Both names contain two upstroke letters in the infix and contain the letter pair 'er' immediately following the second upstroke letter 'd'.	Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Lidoderm does not overlap with the strengths of Tecfidera. Dosage: Tecfidera is available in a starter pack in which it may be prescribed as 'use as directed'. Although both products may be prescribed as 'use as directed', the prescription for Tecfidera would need to indicate "starter pack" and may minimize the risk of confusion between the names.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Taladine (Ranitidine) Capsules Strength: 150 mg Dosage: One capsule by mouth one to four times daily	Orthographic: Both names begin with the letter 'T' and contain two upstroke letters in the infix. The letter 'a' at the second position in Taladine and the letter 'e' at the second position in Tecfidera look similar when scripted. The letter string 'ine' in Taladine and the letter string 'era' in Tecfidera looks similar when scripted. Dosage, dosage form, and route of administration: Both products can be prescribed as 'One capsule by mouth.' Frequency of administration: Both products can be administered twice daily.	Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Taladine does not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Tirofiban Injection Strength: 50 mcg per mL Dosage: 0.4 mcg/kg/minute intravenously for 30 minutes followed by 0.1 mcg/kg/minute intravenously; 0.2 mcg/kg/minute intravenously for 30 minutes followed by 0.05 mcg/kg/minute intravenously	Orthographic: Both names begin with the letter 'T' and contain the letter pair 'fi' in the infix and a second upstroke letter in the infix. The letter pair 'ir' in Tirofiban and the letter pair 'ec' in Tecfidera look similar when scripted. The letter pair 'an' in Tirofiban and the letter pair 'er' in Tecfidera look similar when scripted.	Orthographic: The prefix 'Tiro' in Tirofiban contains an extra rounded letter 'o' giving it a longer appearance than the prefix 'Tec' in Tecfidera. Frequency of administration and unit of measurement: Tirofiban is administered as a continuous infusion ordered by a titrated mcg/minute dosage vs. Tecfidera is administered twice daily ordered by a fixed mg dosage.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Terfenadine Tablet Strength: 60 mg Dosage: One tablet by mouth twice daily Terfenadine was withdrawn from the U.S. market due to serious drug interactions and approval of a safer alternative drug, Fexofenadine.	Orthographic: Both names begin with the letters 'Te' and contain a cross stroke letter 'f' at the fourth position and an upstroke letter 'd' in the infix. The letter string 'ine' in Terfenadine and the letter string 'era' in Tecfidera look similar when scripted. Dosage and route of administration: Both products can be prescribed as 'Take one by mouth.' Frequency of administration: Both products are administered twice daily	Orthographic: Terfenadine contains the letter string 'ena' between the cross stroke letter 'f' and the upstroke letter 'd' giving the name a longer appearance compared to Tecfidera which only contains the narrow letter 'i' between the cross stroke letter 'f' and the upstroke letter 'd.' Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Terfenadine does not overlap with the strengths of Tecfidera. The 120 mg strength of Tecfidera can be achieved with two tablets of Terfenadine 60 mg, but a dosage of Terfenadine 120 mg is outside of the usual dosage range.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Lofibra (Fenofibrate) Capsules and Tablets Strength: 67 mg, 134 mg, 200 mg Capsules; 54 mg, 160 mg Tablets Dosage: One capsule or one tablet by mouth once daily	Orthographic: The first two letters 'Lo' and 'Te' look similar when scripted. Both names contain the letter pair 'fi' and another upstroke letter in the infix and end with the letter pair 'ra.' Dosage, dosage form, and route of administration: Both products can be prescribed as 'Take one capsule by mouth.'	Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. The strengths of Tecfidera do not overlap and are not achievable with the strengths or dose of Lofibra.
15.	Zorbtive (Somatropin) Powder for Injection Strength: 8.8 mg Dosage: 0.1 mg/kg (up to a maximum of 8 mg) subcutaneously once daily	Orthographic: The first three letters 'zor' and 'tec' look similar when scripted. Both names contain an upstroke letter and a cross stroke letter in the infix. The letter string 'ive' in Zorbtive and the letter string 'era' in Tecfidera look similar when scripted.	Orthographic: The letter pair 'bt' in Zorbtive and the letter string 'fid' in Tecfidera look different when scripted. Strength and dosage: The strengths and dosages of Zorbtive and Tecfidera do not overlap. There is numerical similarity between the dosage Zorbtive 12 mg and Tecfidera 120 mg, but a dosage of Zorbtive 12 mg is outside of the usual dosage range.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Ticlopidine Tablets Strength: 250 mg Dosage: One tablet by mouth twice daily	Orthographic: Both names begin with the letter 'T,' contain the letter 'c' at the third position followed by an upstroke letter. The letter string 'ine' in Ticlodipine and the letter string 'era' in Tecfidera look similar when scripted. Dosage, route of administration, and frequency of administration: Both products can be prescribed as 'Take one by mouth twice daily.'	Orthographic: Ticlopidine contains a down stroke letter in the infix vs. Tecfidera does not contain any down stroke letters in the infix. Ticlopidine contains the letter string 'opi' between the upstroke letter 'l' and the upstroke letter 'd' giving the name a longer appearance compared to Tecfidera which only contains the narrow letter 'i' between the cross stroke letter 'f' and the upstroke letter 'd.' Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Ticlopidine does not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Terbinafine Tablets, Cream Strength: 250 mg Tablets; 1% Cream Dosage: One tablet by mouth once daily; Apply to affected area twice daily	Orthographic: Both names begin with 'Te' and contain an upstroke letter and a cross stroke letter in the infix. The letter string 'ine' in Terbinafine and the letter string 'era' in Tecfidera look similar when scripted. Dosage and route of administration: Both products can be prescribed as 'Take one by mouth.'	Orthographic: Terbinafine contains the letter string 'ina' between the upstroke letter 'b' and the cross stroke letter 'f' giving the name a longer appearance compared to Tecfidera which only contains the narrow letter 'i' between the cross stroke letter 'f' and the upstroke letter 'd.' Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strengths of Terbinafine do not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Bifidus (Bifidobacterium bifidum) Capsules Strength: 3 Billion Colony Forming Units Dosage: Two capsules by mouth daily	Orthographic: The first two letters 'bi' and 'te' can look similar when scripted. Both names contain the letter string 'fid.' The letter 'u' in Bifidus may look similar to the letter pair 'er' in Tecfidera. Dosage form and route of administration: Both products are capsules administered orally.	Orthographic: The prefix 'Tec' in Tecfidera contains an extra rounded letter 'c' giving it a longer appearance than the prefix 'Bi' in Bifidus. Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Bifidus does not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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.	Profiderall (Niacin, Vitamin B 5, Vitamin B6, Vitamin B12, and Cognitive Energy Complex) Capsules Strength: Niacin 10 mg, Vitamin B5 20 mg, Vitamin B620 mg, Vitamin B12 500 mcg, and Cognitive Energy Complex 1,316 mg Dosage: Two capsules by mouth every 8 hours as needed	Orthographic: The first two letters 'Pr' and 'Te' can look similar when scripted. Both names contain the letter string 'fidera.' Dosage form and route of administration: Both products are capsules administered orally.	Orthographic: Profiderall has two upstroke letters in the suffix vs. Tecfidera does not have any upstroke letters in the suffix, giving the Profiderall a longer length and a different shape compared to Tecfidera. Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Profiderall does not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
20.	Actidose with Sorbitol (Activated Charcoal) Suspension Strength: 25 g per 120 mL, 50 g per 240 mL Dosage: 50 g as a single dose Actidose-Aqua (Activated Charcoal) Suspension Strength: 15 g per 72 mL, 25 g per 120 mL, 50 g per 240 mL Dosage: 25 g to 100 g per dose every 4 to 6 hours as needed; 1 g/kg/dose to 2 g/kg/dose every 4 to 6 hours in children	Orthographic: The first letter 'A' and 't' look similar when scripted. Both names contain the letter 'c' followed by a cross stroke letter and the letter pair 'id.' The letter string 'ose' in Actidose and the letter string 'era' in Tecfidera look similar when scripted. Dosage: There is numerical similarity between Actidose-Aqua 24 g (24 kg child given 1 g/kg/dose) and Tecfidera 240 mg.	Orthographic: A prescription for Actidose would need to indicate with Sorbitol or Aqua, since the root name Actidose does not exist. The need to specify which Actidose product to dispense would differentiate the two names. Frequency of administration: Actidose with Sorbitol is administered as a one time dose and Actidose-Aqua is administered every 4 to 6 hours as needed vs. Tecfidera is administered twice daily.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
21.	Barbidonna (Atropine Sulfate, Hyoscyamine, Phenobarbital, and Scopolamine Hydrobromide) Tablets Strength: Atropine Sulfate 0.025 mg, Hyoscyamine Sulfate 0.1286 mg, Phenobarbital 16.2 mg, and Scopolamine Hydrobromide 0.0074 mg Dosage: One to two tablets by mouth three to four times daily	Orthographic: The first four letters 'barb' and 'tecf' can look similar when scripted. Both names contain the letter pair 'id' starting at the fifth position. The letter pair 'on' in Barbidonna and the letter pair 'er' in Tecfidera look similar when scripted. Both names end with the letter 'a' Dosage and route of administration: Both products can be prescribed as 'Take one by mouth.'	Orthographic: The letter string 'onn' in the suffix of Barbidonna appears different from the letter string 'er' in Tecfidera and is longer when scripted. Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Barbidonna does not overlap with the strengths of Tecfidera.
22.	Lubriderm Products: Daily Moisture Advanced Therapy Intense Skin Repair Men's Line Soothing Relief	Orthographic: The first letter 'L' and 'T' look similar when scripted. The letter 'u' in Lubriderm and the letter pair 'ec' in Tecfidera look similar when scripted. The letter 'b' in Lubriderm and the letter 'f' in Tecfidera look similar when scripted. Both names contain the letter string 'ider' starting in the infix.	Orthographic: Lubriderm is available with five different product lines: Daily Moisture, Advanced Therapy, Intense Skin Repair, Men's Line, and Soothing Relief. A prescription for Lubriderm would need to indicate which product is intended to be prescribed. Additionally, within each product line are different products (i.e. lotion, lotion with SPF 15, etc.). The need to specify which Lubriderm product is intended to be prescribed would differentiate the two names.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
23.	(b) (4)		

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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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
24.	Rebif Rebidose[***] (Interferon Beta-1A) Injection Strength: 8.8 mcg per 0.2 mL, 22 mcg per 0.5 mL, 44 mcg per 0.5 mL Dosage: 20% of the prescribed dose subcutaneously three times a week for two weeks, then 50% of the prescribed dose subcutaneously three times a week for two weeks, then the prescribed dose, 22 mcg or 44 mcg, three times a week	Orthographic: Comparing the modifier 'Rebidose[***]' to Tecfidera, both names contain the letter 'e' at the second position and the letter pair 'id' in the infix. The letter 'b' in Rebidose[***] and the letter 'f' in Tecfidera look similar when scripted. The letter pair 'ose' in Rebidose[***] and the letter pair 'era' in Tecfidera look similar when scripted. Strength: Both products are available in a starter or titration pack, in which a strength would not be specified on a prescription. Dosage: Both products can be prescribed as 'Use as directed' for the starter or titration pack.	Orthographic: The first letter 'r' and 't' look different when scripted. The prefix 'tec' in Tecfidera contains an extra rounded letter 'c' giving it a longer appearance than the prefix 're' in Rebidose[***]. The entire name Rebif Rebidose[***] looks different from Tecfidera when scripted.

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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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
25.	Taxotere (Docetaxel) Injection Strength: 20 mg per 0.5 mL, 20 mg per mL, 80 mg per 2 mL, 80 mg per 4 mL Dosage: 60 mg/m^2 to 100 mg/m^2 intravenously every 3 weeks	Orthographic: Both names begin with the letter 'T' and both names contain an upstroke letter in the infix followed by the letter pair 'er.' Phonetic: The first syllable 'Tec' and 'Tax' can sound similar when spoken. The third syllable 'der' and 'ter' sound similar when spoken. Dosage: There is numerical overlap between Tecfidera 120 mg and Taxtoere 120 mg (75 mg/m^2 dosage in a 1.6 m^2 patient)	Orthographic: Tecfidera contains two upstroke letters in the infix vs. Taxotere contains one upstroke letter in the infix giving the names a different shape when scripted. Phonetic: Tecfidera contains four syllables vs. Taxotere contains three syllables. The fourth syllable 'a' in Tecfidera is distinct. Frequency of administration: Taxotere is administered every 3 weeks vs. Tecfidera is administered twice daily.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
26.	Zaditor (Ketotifen) Solution Strength: 0.025% Dosage: One drop in the affected eye every 8 to 12 hours	Orthographic: The first two letters 'za' and 'te' look similar when scripted. Both names contain two upstroke letters in the infix. The letter pair 'or' in Zaditor and the letter pair 'er' in Tecfidera look similar when scripted. Frequency of administration: Both products can be administered twice daily	Orthographic: The cross stroke letter 't' in Zaditor and the upstroke letter 'd' in Tecfidera look different when scripted. Tecfidera contains an additional letter 'a' in the suffix, giving it a longer length compared to Zaditor. Strength: Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. In addition, if written, the strength of Zaditor does not overlap with the strengths of Tecfidera.

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.			
No.	**Proposed name:** Tecfidera **Dosage Form:** Delayed-release Capsules **Strength:** 120 mg, 240 mg, or Starter Pack **Dosage:** One capsule by mouth twice daily or Use as directed	**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**
27.	Lubrifair (Mineral Oil and Petrolatum) Ointment <u>Dosage:</u> Apply a small amount to the inside of the lower lid one to four times daily as needed	<u>Orthographic:</u> The first letter 'L' and 'T' look similar when scripted. The letter 'u' in Lubrifair and the letter pair 'ec' in Tecfidera look similar when scripted. Both names contain an upstroke letter and a cross stroke letter in the infix. The letter pair 'ai' in Lubrifair and the letter pair 'er' in Tecfidera look similar when scripted.	<u>Orthographic:</u> The cross stroke letter 'f' in Lubrifair and the upstroke letter 'd' in Tecfidera look different when scripted. <u>Strength:</u> Tecfidera is available in a 120 mg and 240 mg strength, and a starter pack in which a strength would not be specified. Although both products may be written without a strength, the prescription for Tecfidera would need to indicate "starter pack" in order to not specify a strength, which may minimize the risk of confusion between the names. <u>Dosage:</u> Tecfidera is available in a starter pack in which it may be prescribed as 'use as directed'. Although both products may be prescribed as 'use as directed', the prescription for Tecfidera would need to indicate "starter pack" and may minimize the risk of confusion between the names.

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/s/

JULIE V NESHIEWAT
01/16/2013

CAROL A HOLQUIST
01/16/2013

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:	August 23, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPH Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	(b) (4) (Dimethyl Fumarate) Delayed-release Capsules 120 mg, 240 mg
Application Type/Number:	NDA 204063
Applicant/Sponsor:	Biogen Idec
OSE RCM #:	2012-1263

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08/23/2012

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08/23/2012

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08/23/2012

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 23, 2012
Reviewer:	Julie Neshiewat, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Irene Z. Chan, PharmD, BCPS Division of Medication Error Prevention and Analysis
Deputy Director:	Kellie Taylor, PharmD, MPh Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	(b) (4) (Dimethyl Fumarate) Delayed-release Capsules 120 mg, 240 mg
Application Type/Number:	NDA 204063
Applicant/Sponsor:	Biogen Idec
OSE RCM #:	2012-542

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JULIE V NESHIEWAT
05/23/2012

IRENE Z CHAN
05/23/2012

CAROL A HOLQUIST on behalf of KELLIE A TAYLOR
05/24/2012

CAROL A HOLQUIST
05/24/2012