# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-527**

# 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**

| | |
|---|---|
| Date: | August 23, 2010 |
| Application Type/Number: | NDA# 022527 |
| Through: | Todd Bridges, RPh, Team Leader<br>Denise Toyer, PharmD, Deputy Director<br>Division of Medication Error Prevention and Analysis |
| From: | Denise V. Baugh, PharmD, BCPS, Safety Evaluator<br>Division of Medication Error Prevention and Analysis |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Gilenya (Fingolimod) Capsules<br>0.5 mg |
| Applicant: | Novartis |
| OSE RCM #: | 2010-1165 |

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

# CONTENTS

## EXECUTIVE SUMMARY

This review summarizes the analysis of the proposed proprietary name Gilenya for Fingolimod Capsules. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus DEMPA finds the proposed propriety name, Gilenya, acceptable for this product. DMEPA considers this a final review, however, if approval of the NDA is delayed beyond 90 days from the date of this review, the proposed proprietary name, Gilenya, must be re-evaluated.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

## 1 BACKGROUND

### 1.1 INTRODUCTION

This review summarizes the Division of Medication Error Prevention and Analysis' risk assessment for the proposed proprietary name, Gilenya (Fingolimod) Capsules. The Applicant, Novartis, requested an assessment of the proposed proprietary name in a submission dated May 24, 2010. The Division of Medication Error Prevention and Analysis (DMEPA) assesses a proposed proprietary name regarding its potential for name confusion with other proprietary or established drug names in the usual practice settings. Additionally, DMEPA considers the Division of Drug Marketing, Advertising and Communications' (DDMAC's) promotional assessment of the name.

The Applicant submitted an independent name analysis conducted by (b) (4) for the name, 'Gilenya', and the analysis was evaluated as part of this review. Additionally, the Applicant submitted revised container labels and carton labeling with the proposed name, 'Gilenya', affixed to them as requested in OSE Review# 2010-355 dated May 24, 2010.

### 1.2 REGULATORY HISTORY

DMEPA initially reviewed the proposed name, 'Gilenia', in the IND phase and found the name acceptable (OSE review #2007-1406, dated May 5, 2009) based upon the product characteristics submitted with the IND. At that time, the Applicant (b) (4) for the product (0.5 mg (b) (4) When the NDA was submitted (February 8, 2010), the Applicant proposed (b) (4) product strength (0.5 mg). Upon re-review of the name, DMEPA found the name unacceptable (OSE# 2010-354 dated May 4, 2010) (b) (4) The Applicant now proposes an alternative proprietary name, 'Gilenya', which was submitted May 24, 2010.

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

### 1.3 PRODUCT INFORMATION

Gilenya (fingolimod) capsules are indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. It will be available in hard gelatin capsules of 0.5 mg and administered by mouth once daily. Gilenya will be supplied in blister packs of (b) (4) 28 capsules. Gilenya capsules should be stored at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Capsules should be protected from moisture.

## 2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Gilenya.

### 2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'G' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Gilenya, DMEPA also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (2, capital letter 'G' and lower case 'l'), downstrokes (one, lower case 'y'), cross-strokes (none), and dotted letters (1, lower case 'i). Additionally, several letters in Gilenya may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Gilenya.

When searching to identify potential names that may sound similar to Gilenya, DMEPA searches for names with a similar number of syllables (three), stresses (GIL-en-ya, gil-EN-ya or gil-en-ē-a), and placement of vowel and consonant sounds. Additionally, The DMEPA staff considers that pronunciation of parts of the name can vary such as 'Gil-' may be interpreted as 'Jil-' and the 'y' may be pronounced as an 'i' (see Appendix B). The Applicant's intended pronunciation (je-LEN-yah) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

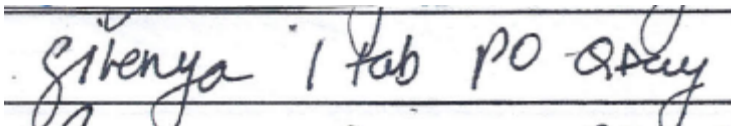
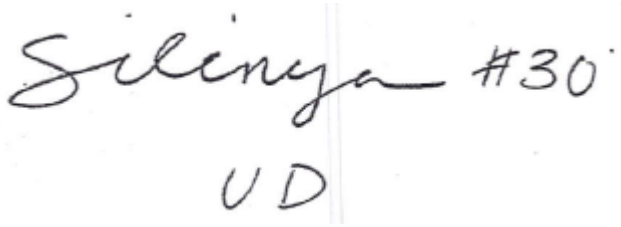
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

## 2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescriptions were communicated during the FDA prescription studies.

**Figure 1. Gilenya Prescription Written Studies (conducted June 18, 2010) and Voice Study (conducted August 3, 2010)**

| MEDICATION ORDER and HANDWRITTEN PRESCRIPTION | VERBAL INPATIENT ORDER |
|---|---|
| Inpatient Medication Order:<br>  <br> | Gilenya #30<br>Give as directed. |
| Outpatient Prescription Order:<br>  <br> | |

## 2.3 EXTERNAL PROPRIETARY RISK ASSESSMENT

For Gilenya, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

## 3 RESULTS

The names identified from DMEPA's methods as potential sources for name confusion with Gilenya are listed below.

### 3.1 DATABASE AND INFORMATION SOURCES

The safety evaluator searches of database and DMEPA information sources yielded a total of 20 names as having some similarity to the name Gilenya.

Sixteen names identified were thought to look like Gilenya (Gelnique, Relenza, Acanya, Gen-Lanta, Selenium, Selenos, Silexin, Silicia, Silicea, Salacyn, Celexa, Salagen, Salonpas, Silenor, Solage, and Solaraze). One name (Clenia) was thought to sound similar to Gilenya. Three names were thought to look and sound similar to Gilenya: Gilenya, Jacenya, and Gillenia.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of July 26, 2010.

### 3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by the DMEPA staff (see section 3.1), and noted two additional names, Syncria and Jenloga, thought to have orthographic and/or phonetic similarity to Gilenya.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

### 3.3 FDA PRESCRIPTION ANALYSIS STUDIES

Twenty-nine practitioners responded and none of the responses overlapped with existing names. One participant interpreted the name correctly as 'Gilenya', with the correct interpretation occurring only in the inpatient prescription study. Misinterpretations in the written studies included lower case 'l' being misinterpreted as 'b' or 'v'. In the verbal studies, the responses were misspelled phonetic variations of the proposed name, Gilenya, including 'G' being misinterpreted as 'J'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

### 3.4 EXTERNAL STUDY

The proprietary name risk assessment submitted by the Applicant found the name, Gilenya, moderately vulnerable to medication errors due to its "slight look-alike similarity with Relenza".

### 3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified no additional names which were thought to look and/or sound similar to Gilenya and represent a potential source of drug name confusion.

Since the proposed name, Gilenya, resembles the previously proposed name, Gilenia, we also evaluated nineteen names from our previous review (OSE Review # 2010-354 dated May 4, 2010) for their similarity to Gilenya. Thus, we identified a total of 41 names for their similarity to the proposed name, Gilenya.

### 3.6 COMMENTS FROM THE DIVISION OF NEUROLOGY PRODUCTS (DNP)

#### *3.6.1 Initial Phase of Review*

In response to the OSE June 2, 2010, email, the Division of Neurology Products did not have any concerns with the proposed proprietary name, Gilenya.

#### *3.6.2 Midpoint of Review*

On August 18, 2010, DMEPA notified DNP via email that we find the name Gilenya acceptable. Per email correspondence from DNP on August 20, 2010, they agreed with our recommendation and did not have any additional comments.

## 4 DISCUSSION

This proposed name, Gilenya, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

### 4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. The Division of Neurology Products and DMEPA concurred with the promotional assessment.

### 4.2 SAFETY ASSESSMENT

DMEPA identified 41 names for their potential similarity to the proposed name, Gilenya. We did not identify other aspects of the name that would function as a source of error. We note that one of the 41 names, Silexin, was found to be the proprietary name for two different products. Silexin is a nutritional supplement and Silexin is a cough and cold product. Although Silexin is the proprietary name for two different products, this name was evaluated as one name.

Twenty-three of the 41 names were eliminated from further evaluation for the following reasons: seventeen names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name, one name is the subject of this review, one name was not reviewed by the Agency and two names were found in one database but no other information was found in any of the other commonly used databases. Additionally, two names, 'Gilenia' (b) (4), were previously proposed names found to be unacceptable by DMEPA and thus were never marketed (see Appendices D through I).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 18 names and lead to medication errors. This analysis determined that the name similarity between Gilenya and all 18 names identified was unlikely to result in medication errors for the reasons presented in Appendices J through L.

## 5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Gilenya, is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) have no objection to the proprietary name, Gilenya, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified of DMEPA's decision via letter.

## 6 COMMENTS TO THE APPLICANT

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

## 7 REFERENCES

***OSE Review:***

Park, J. OSE Review #2007-1406, Proprietary Name Review for Gilenia dated May 5, 2009.

Duffy, F. OSE Review #2010-354, Proprietary Name Review for Gilenia dated May 4, 2010.

***1. Micromedex Integrated Index***
***(http://inside.fda.gov/Library/ElectronicResourcesWebLERN/Alphabeticallist/index.htm)***

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

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

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. This is a database which was created for DMEPA, FDA.

***3. Drug Facts and Comparisons, online version, St. Louis, MO***
***(http://inside.fda.gov/Library/ElectronicResourcesWebLERN/Alphabeticallist/index.htm)***

Drug Facts and Comparisons is a compendium organized by therapeutic Course; contains monographs on prescription and OTC drugs, with charts comparing similar products.

***4. FDA Document Achieving, 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 Error Prevention proprietary name consultation requests***

This is a list of proposed and pending names that is generated by DMEPA 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 and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologicals, discontinued drugs and "Chemical Type 6" approvals.

***7. Electronic online version of the FDA Orange Book***
***(http://www.fda.gov/cder/ob/default.htm)***

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

***8. US Patent and Trademark Office location http://www.uspto.gov.***

Provides information regarding patent and trademarks.

***9. Clinical Pharmacology Online***
***(http://inside.fda.gov/Library/ElectronicResourcesWebLERN/Alphabeticallist/index.htm)***

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

***10. 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 tradenames that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

***11. Natural Medicines Comprehensive Databases***
***(http://inside.fda.gov/Library/ElectronicResourcesWebLERN/Alphabeticallist/index.htm)***

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

***12. Stat!Ref***
***(http://inside.fda.gov/Library/ElectronicResourcesWebLERN/Alphabeticallist/index.htm)***

Contains full-text information from approximately 30 texts. Includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology and Dictionary of Medical Acronyms Abbreviations.

***13. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)***

List contains all the recognized USAN stems.

***14. Red Book Pharmacy's Fundamental Reference***

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

***15. Lexi-Comp (www.pharmacist.com)***

A web-based searchable version of the Drug Information Handbook.

***16. Medical Abbreviations Book***

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment 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 focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug 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.

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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and

---

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

[4] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such 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). In addition, the DMEPA staff 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. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

**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<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name<br>Upstrokes<br>Down strokes<br>Cross-strokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound- | Phonetic similarity | Identical prefix<br>Identical infix | • Names may sound similar when pronounced and lead to drug name |

[5] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

| | | | |
|---|---|---|---|
| alike | | Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | confusion in verbal communication |

Lastly, the DMEPA staff also 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 staff conducts searches of 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 using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

### 5. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

### 5. FDA Prescription Analysis 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

### 5. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

## 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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.[6] 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 characteristics listed in Section one. 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.

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

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?"***

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. 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.

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 Risk Assessment:

1. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC'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)].
2. 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)].
3. 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.
4. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
5. 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.

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 is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Applicant 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. However, the safety concerns set forth in criteria a through e 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 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 a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant 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 Applicants' 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. . (See Section 4 for limitations of the process).

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 is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to 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 Applicant 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.

**Appendix B:** Possible orthographic and/or phonetic misinterpretation of letters in the proposed name, Gilenya.

| Letters in Name, Gilenya | Scripted may appear as | Spoken may be interpreted as |
|---|---|---|
| Capital 'G' | 'A', 'C', 'Ci', 'Cr', 'Cu', 'L', or 'S' | 'D', 'J', or 'Z' |
| lower case 'g' | 'f', 'j', or 's' | same as above |
| lower case 'i' | 'e', 'r', or 'u' | any vowel |
| lower case 'l' | 'e' or 't' | |
| lower case 'e' | 'a', 'c', 'i', or 'l' | any vowel |
| lower case 'n' | 'r', 'u', 'v' | 'm' |
| lower case 'y' | 'g', 'j' | |
| lower case 'a' | c, 'ce,' 'ci,' 'el,' or x | any vowel |

**Appendix C:** FDA Prescription Study Responses for Gilenya.

| Inpatient Prescription | Outpatient Prescription | Verbal Prescription |
|---|---|---|
| Givenya | Silinya | Jillenia |
| Gilenya | Silinya | Giletia |
| Givenya | Silinya | |
| Givenya | Silinya | |
| Sibenya | Silenya | |
| Givenya | Silinya | |
| Givenyz | Silinya | |
| Gibenyz | Silinya | |
| Gibenyo | Silinya | |
| Girenya | Silinya | |
| Syneria | Silinya | |
| Givenya | Silenya | |
| Gibenya | Silinya | |
| Givenya | | |

**Appendix D:** Proprietary names that lack convincing orthographic and/or phonetic similarities.

| Proprietary Name | Similarity to Gilenya |
|---|---|
| Acanya | Look-Alike |
| Celexa | Look-alike |
| Syncria | Look-alike |
| Dilantin | Look-alike |
| Sildec | Look-alike |
| Silain | Look-alike |
| (b) (4) | Look-alike |
| | Look-alike |
| | Look-alike |
| Ralivia*** | Look-alike |
| Seldane | Look-alike |
| Selenase | Look-alike |
| Selenium | Look-alike and Sound-alike |
| Selfemra | Look-alike |
| Selsun | Look-alike |
| Selenos | Look-alike |
| Soliris | Look-alike |

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

**Appendix E.** Product names that have not ever been marketed.

| Proprietary Name | Similarity to Gilenya | Status of product name |
|---|---|---|
| Gilenia*** | Look and Sound | Gilenia*** was the previous proposed name for this product. DMEPA objected to the name (b) (4) The name Gilenia*** is no longer actively under consideration. |
| (b) (4) | | |

**Appendix F:** Proprietary names that were not reviewed by the Agency.

| Proprietary Name | Similarity to Gilenya | Reason for not being reviewed |
|---|---|---|
| (b) (4) | | |

**Appendix G:** Proprietary name which is the subject of this review.

| Proprietary Name | Similarity to Gilenya | Source |
|---|---|---|
| Gilenya | Look/Sound | Google |

**Appendix H:** Proprietary name found in Micromedex database and Google search, but no product characteristics or other information was found in any of the other commonly used databases listed in the Reference section (section 7) of this review.

| Proprietary Name | Similarity to Gilenya | Status |
|---|---|---|
| Silexin (Vitamin E, Vitamin D3, Selenium, Lycopene and Decaffeinated Green Tea Leaf Extract OR Guaifenesin/Dextromethorphan OR Benzocaine/Dextromethorphan) | Look | None of the products appear to be marketed. |

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

**Appendix I:** Proprietary name found in USPTO database, but no product characteristics or other information was found in any of the other commonly used databases listed in the Reference section (section 7) of this review.

| Proprietary Name | Similarity to Gilenya | Comments |
|---|---|---|
| Jacenya | Look and Sound | Trademark is owned by a pharmaceutical company in India and is designated for an oral contraceptive or hormonal drug product. |

**Appendix J:** Names of products with no overlap in strength and/or dose and different product characteristics.

| Product name with potential for confusion | Similarity to proposed proprietary name | Strength | Usual Dose (if applicable) | Other Differentiating Product Characteristics |
|---|---|---|---|---|
| **Gilenya (fingolimod) Capsule** | | **0.5 mg** | **One capsule orally daily** | **Route of administration:Oral**<br>**Dosage Form: Capsule**<br>**Indication: Multiple Sclerosis** |
| Gen-Lanta (aluminum/magnesium antacid/simethicone) Oral Solution<br>Used to treat symptoms of too much stomach acid or extra gas | Look | Not specified | Take this medication by mouth usually after meals and at bedtime as needed. Follow directions on product package. (Dose not specified). | **Dosage form:**<br>Solution vs. Capsule<br>**Frequency of Administration**:<br>After meals and at bedtime vs. once daily |
| Gillenia (Gillenia trifoliate) | Look/Sound | Not available | Not available | Gillenia is a plant used as tea or tonic. |
| Silicea (silicon) | Look | Not available | Not available | A natural medicine containing silicon and used for osteoporosis; no recommended daily allowance for silicon since an essential biological role for it has not been identified. |
| Silicia (also known as silicium) | Look | Not available | Not available | A natural medicine containing silicon and used for osteoporosis; no recommended daily allowance for silicon since an essential biological role for it has not been identified. |

**Appendix K:** Drug names with single strength availability but with differentiating product characteristics

| Product name with potential for confusion | Similarity to Product Name | Strength | Usual Dose | Other Differentiating Product Characteristics |
|---|---|---|---|---|
| **Gilenya (Fingolimod) Capsule** | | **0.5 mg** | **0.5 mg (1 capsule) po daily** | |
| Gelclair (glycyrrehtinic acid/providone/ sodium hyaluronate) Oral Gel | Look | NA<br>(15 mL single-use packets) | Pour entire contents of 1 packet into a glass of water and mix with 1 tablespoon (15 mL) of water. Stir well. If no water is available, you may use undiluted. Rinse or swish in mouth for at least 1 minute. Gargle and spit out. | **Dosage form:**<br>Oral gel vs. capsule<br>**Frequency of administration:**<br>Three times a day vs. once daily<br>**Dosing instructions:**<br>See instructions to the left vs. once daily<br><br>Orthographic differences: The proposed name 'Gilenya' contains a down stroke ('y') whereas the name 'Gelclair' contains two up-strokes. These differences will likely differentiate these names from each other when written. |
| Gelnique (Oxybutynin chloride) Gel | Look | 10% | Apply 1 g (1 sachet) once daily to dry, intact skin on the abdomen, upper arms/shoulders, or thighs | **Dosage form:**<br>Gel vs. capsule<br>**Route of administration:**<br>Topical vs. oral |
| Solage (Mequinol and Tretinoin) Topical Solution | Look | 2%/0.01% | Apply directly to the affected area(s) morning and evening (at least 8 hours apart) using the solution applicator. | **Dosage form**:<br>Solution vs. capsule<br><br>**Route of administration**:<br>Topical vs. oral<br><br>**Frequency of administration**:<br>Morning and evening vs. once daily |
| Salacyn (salicylic acid) Topical Lotion, Topical Cream | Look | 6% | Apply to affected area. Improvement in warts should occur in 1 to 2 weeks (The reader is referred to individual product labeling for specific instructions for use of these products). | **Dosage form**:<br>lotion, cream vs. capsule<br><br>**Route of Administration**:<br>Topical vs. oral |

| | | | | |
|---|---|---|---|---|
| Salonpas (methol; methyl salicylate) Topical Patch | Look | 3%/10% | Apply one patch to the affected area and leave in place for up to 8 to 12 hours. If pain persists after using the first patch, a second patch may be applied for up to 8 to 12 hours. Use only one patch at a time. Do not use more than 2 patches per day. | **Dosage form**:<br>Patch vs. tablet<br><br>**Route of Administration:**<br>Topical vs. oral<br><br>**Frequency of Administration**:<br>once daily for up to 8 to 12 hours vs. once daily |
| Solaraze (diclofenac sodium) Topical Gel | Look | 3% | Apply gel to lesion areas twice daily. Assure enough gel is applied to adequately cover each lesion. | **Dosage Form**:<br>Gel vs. Capsule<br><br>**Route of Administration**:<br>Topical vs. oral<br><br>**Frequency of administration**:<br>Twice daily vs. once daily |
| Clenia (Sulfacetamide Sodium and Sulfur) Topical Cream | Look | 10%/5% | Apply a thin film to affected areas 1 to 3 times daily. Massage lightly to blend into skin. | **Dosage form:**<br>Cream vs. Capsule<br><br>**Route of Administration:**<br>Topical vs. oral<br><br>Additionally, although this name was found to be confusing with the previously proposed name, Gilenia, this name (Gilenya) has a down stroke and appears longer than Clenia. Both of these variables are likely to distinguish these names (Clenia vs. Gilenya) from each other. |

**Appendix L:** Risk of medication errors due to product confusion minimized by dissimilarity of names or use in clinical practice for reasons described below.

| **Proposed name:**<br>**Gilenya**<br><br>**(Fingolimod HCl) Capsules** | **Strength:**<br>**0.5 mg** | **Usual Dose:**<br><br>**0.5 mg orally once daily** |
|---|---|---|
| **Failure Mode: Name confusion** | **Causes (could be multiple)** | **Rationale** |
| Relenza<br>(Zanamivir) powder for inhalation<br><br>5 mg<br><br>Usual dose:<br><br>Treatment -<br><br>10 mg twice daily for 5 days<br><br>Prophylaxis -<br><br>10 mg once daily for 10 days; or for 28 days<br><br>(10 mg dose is provided by 2 inhalations [one 5 mg blister per inhalation]).<br><br>For treatment and prophylaxis of influenza. | Orthographic similarities stem from sharing the same infix ('-len-') and last letter (lower case 'a'). Additionally, the second letters ('e' vs. 'I') and down-strokes ('z' vs. 'y') look similar when written.<br><br>Overlapping route of administration (oral) and, potentially the frequency of administration (once daily).<br><br>Also, this name pair has overlapping numerical strengths (5 mg vs. 0.5 mg). | Orthographic differences may help to minimize the potential for medication error in the usual practice setting.<br><br>*Rationale:*<br><br>Although Relenza and Gilenya share some orthographic similiarities, their first letters ('R' vs. 'G') help to distinguish these names from each other.<br><br>Despite the overlapping numerical strength, the dispensing/administration of ten 0.5 mg capsules may alert the healthcare professional to question the intent of the prescriber. |
| Salagen (pilocarpine hydrochloride) Oral Tablets<br><br>5 mg, 7.5 mg<br><br>Usual dose for dry mouth in head and neck cancer patients:<br><br>5 mg three times daily | Orthographic similarity stems from the fact that upper case 'S' looks similar to upper case 'G' when written and both name pairs share an up- stroke (lower case 'l') and a down-stroke ('g' vs. 'y') in the same or similar positions. Additionally, lower case letters 'a', 'e', and 'I' may look similar orthographically.<br><br>Shared product characteristics include dosage form (capsule/tablet) and route of administration (oral).<br><br>There is also a potential numerical overlap in strengths (5 mg vs. 0.5 mg). | Orthographic differences may help to minimize the potential for medication error in the usual practice setting.<br><br>*Rationale:*<br><br>This name pair is unlikely to be confused because the suffix in 'Salagen' appears longer than that of 'Gilenya'. These differences are likely to minimize confusion between Salagen and Gilenya. Additionally, the prescriber would have to identify the strength if the intended drug were Salagen, and Salagen is administered three times daily whereas Gilenya is given once daily in the usual settings. |

| | | |
|---|---|---|
| Jenloga (clonidine hydrochloride) Tablets<br>0.1 mg, 0.2 mg<br>0.1 mg tablet at bedtime; increase by 0.1 mg at weekly intervals up to 0.6 mg daily in divided doses to achieve desired blood pressure lowering. | Orthographic similarity stems from having an up stroke ('l') and down-stroke ('g' and 'y') in similar positions in the name as well as having the same last letter ('a').<br>Phonetic similarity stems from both names having three syllables and the similarity between 'j' (Jenloga) and 'g' (Gilenya) when spoken.<br>Shared product characteristics include dosage form (solid oral), route of administration (oral) and potentially frequency of administration (daily).<br>Additionally, the strength of 0.5 mg of Gilenya is achievable with Jenloga. | Confusion leading to medication errors is unlikely to occur in the usual practice settings.<br>*Rationale:*<br>The first letter in their names ('J' vs. 'G') does not look alike when written. Additionally, the position of the upstroke (lower case 'l') in these names appears to be significantly different due to the spacing between their first letters and the upstroke. This distinction, Jenloga vs. Gilenya, is likely to distinguish these names from each other.<br>Phonetically, the second syllables in these names sound different when spoken (Jen-LO-ga vs. Gi-LEN-ya) which will likely assist in distinguishing these names from each other.<br>Furthermore, the prescriber for 'Jenloga' will have to specify the strength before this drug can be dispensed/administered. |
| Januvia<br>(Sitagliptin phosphate) tablets<br>25 mg, 50 mg, 100 mg<br>100 mg by mouth once daily<br>Diabetes mellitus | The sole orthographic similarity between these names is that they end in the same letter ('a').<br>Phonetic similarities:<br>Both names begin with a 'J' sound; both names could be pronounced with 4 syllables; their suffixes rhyme '-via' vs. '-nia'.<br>Overlapping route of administration (oral), and frequency of administration (once daily). | Orthographic and phonetic differences and differentiating product characteristics may help to minimize the potential for medication error in the usual practice setting.<br>*Rationale:*<br>Orthographically, Gilenya contains one up-stroke and one down-stroke whereas the name Januvia has neither. This should distinguish these names from each other.<br>Phonetically, although the names Januvia and Gilenya have some similarities, the second syllables in this name pair sound different ('nuv' in Januvia vs. 'len' in Gilenya) when spoken.<br>Finally, Januvia is available in three strengths. Thus, prescribers must indicate the desired strength for this drug product. Since Gilenya will be available as a single strength, the strength may be omitted however, the strength for this name pair differs (0.5 mg vs. 25 mg, 50 mg, and 100 mg).<br>Despite the overlapping route of administration and frequency of administration, the multiple and different strengths of Januvia as well as phonetic and orthographic differences will help to minimize confusion between Januvia and Gilenya. |

| | | |
|---|---|---|
| Galvus*** (Vildagliptin) Tablets<br>50 mg and 100 mg<br>50 mg to 100 mg by mouth once or twice daily<br>Indicatecd for type 2 diabetes mellitus. | Orthographic similarity:<br>'Gal-' and 'Gil-' may appear similar when scripted; the last letter of each name may appear similar when scripted if the letters trail off ('s' and 'a').<br>Overlapping route of administration (oral), frequency of administration (once daily), both are solid oral dosage forms (tablet/capsule). | Orthographic and product differences will help to minimize the likelihood of medication errors in the usual practice setting.<br>*Rationale*:<br>Orthographically, the proposed name, Gilenya, is longer than the name Galvus*** when written. Additionally, Gilenya contains a down-stroke which is absent in 'Galvus'***. These features should differentiate these names from each other when written.<br>Additionally, although Galvus*** and Gilenya share some overlapping product characteristics (route of administration, frequency of administration, and both are solid oral dosage forms), they will be available in different strengths (50 mg and 100 mg vs. 0.5 mg). Since Galvus*** is available in multiple strengths, the strength must be specified on prescriptions. Contrarily, Gilenya will be available in a single strength and thus, the strength may be omitted on prescriptions. Therefore, the different strengths will help to minimize confusion between Galvus*** and Gilenya. |
| Alinia (nitazoxanide) Tablets 500 mg<br>Indicated for diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum.*<br>Usual dose:<br>One tablet every 12 hours with food for 3 days | Alinia and Gilenya are orthographically similar as their first letters ('A' vs. 'Gi') and infixes ('-lin-' vs '-len-') may appear similar when written.<br>Overlapping product characteristics include dose and dosage form (one tablet/capsule), and route of administration (oral). Since both products are available as single strengths, their strengths may be omitted on a prescription.<br>These names also share numerical overlap in their strengths (500 mg vs. 0.5 mg). | Confusion leading to medication errors is unlikely to occur in the usual practice settings.<br>*Rationale:*<br>Confusion between this name pair is unlikely to occur due to the presence of a down-stroke ('y') in the proposed name, Gilenya. This helps to distinguish these names from each other. Additionally, their frequency of administration (every 12 hours vs. daily) and duration of administration (3 days vs. chronic) differ.<br>Although this name was found to be confusing with the previously proposed name, Gilenia, this name (Gilenya) has a down stroke and appears longer, both of which are likely to distinguish these names (Alinia vs. Gilenya) from each other. |
| Silenor (doxepin hydrochloride) Tablets<br>3 mg, 6 mg<br>Indicated for insomnia:<br>6 mg once daily for adults and 3 mg once daily for the elderly; | Orthographic similarity stems from having 7 letters, sharing the same letters in the same position ('-ilen-') as well as the similarity between their first letters ('S' vs. 'G') when written. | Confusion leading to medication errors is unlikely to occur in the usual practice settings.<br>*Rationale:*<br>The down stroke in the proposed name, Gilenya, distinguishes this name from 'Silenor' and is likely to minimize confusion between these names. Also, Silenor is available in two strengths, whereas |

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

| | | |
|---|---|---|
| take within 30 minutes of bedtime. | Shared product characteristics include solid oral dosage form (tablet/capsule), route of administration (oral), and frequency of administration (daily). | Gilenya will be available as a single strength. Thus, prescriptions for Silenor will need to designate the desired strength to be dispensed. However, the strength may be omitted on prescriptions for Gilenya. In the event the strength for Gilenya is written, it is different from the available strengths of Silenor (0.5 mg vs. 3 mg and 6 mg). Thus, despite the orthographic similarities and some overlapping product characteristics, the product strength will help to minimize the potential for confusion between Silenor and Gilenya. |

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-22527 | ORIG-1 | NOVARTIS PHARMACEUTICALS CORP | FINGOLIMOD HCL ORAL CAPSULES |

---

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

---

/s/

---

DENISE V BAUGH
08/23/2010

TODD D BRIDGES
08/23/2010

DENISE P TOYER
08/23/2010