CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022545Orig1s000

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

Application Type/Number:	NDA 022545
Through:	Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Kristina A. Toliver, PharmD, Team Leader Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Tekamlo (Aliskerin and Amlodipine) Tablets 150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg, 300 mg/10 mg
Applicant:	Novartis Pharmaceuticals Corporation, Inc
OSE RCM #:	2010-644

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1 INTRODUCTION

This re-assessment of the proprietary name responds to the anticipated approval of NDA 022545 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Tekamlo, acceptable in OSE Review #2009-2182, dated February 2, 2010. The Division of Cardiovascular and Renal Products did not have any concerns with the proposed name, Tekamlo, during our initial review. Additionally, the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on November 19, 2009, and May 27, 2010.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 6) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We use the same search criteria outlined in OSE Review #2009-2182, for the proposed proprietary name, Tekamlo. None of the product characteristics for Tekamlo have been altered since our previous review, thus we did not re-evaluate previous names of concern. Additionally, DMEPA searches the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

3 RESULTS

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of August 9, 2010.

However, the safety evaluator searches of the databases listed in Section 5 identified two additional names, Teflaro*** and Tekamlide***, thought to look similar to Tekamlo and represent a potential source of drug name confusion.

Failure mode and effect analysis (FMEA) was applied to determine if the proposed name could potentially be confused with any of the name and lead to medication errors. This analysis determined that the name similarity between Teflaro*** or Tekamlide*** and Tekamlo was unlikely to result in medication errors for the reasons presented in Appendix A.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Tekamlo, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Tekamlo, for this product at this time.

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

5 REFERENCES

1. Jones-Smith, T. OSE Review #2009-2182: Proprietary Name Review for Tekamlo. February 2, 2010.

2. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

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

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

USAN Stems List contains all the recognized USAN stems.

4. Division of Medication Error Prevention and Analysis proprietary name 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.

APPENDIX

Appendix A: Proposed proprietary names that have never been marketed.

Proprietary Name	Similarity to Tekamlo	Reason for Discard
Tekamlide*** (b) (4)	Look	This proposed name was withdrawn by the Applicant and an alternate name submitted.

Appendix B: Products with multiple differentiating product characteristics

Proprietary Name	Similarity to Tekamlo	Reason for Discard
Teflaro*** Ceftaroline for injection 400 mg and 600 mg Usual Dose: 600 mg intravenously every 12 hours	Look	Product characteristic, orthographic and phonetic differences in the names help to minimize the risk of medication errors in the usual practice setting. Rationale: Tekamlo is combination product available in multiple product strengths. Although the 600 mg strength of Teflaro is achievable with the 300 mg aliskerin component of Tekamlo, prescriptions for Tekamlo would include the strengths for both active ingredients which would help differentiate Tekamlo from Teflaro. Although both names have three upstrokes, the last upstroke in Tekamlo appears towards the end of the name vs. Teflaro, whose upstrokes appear in the middle of the name.

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22545	ORIG-1	NOVARTIS PHARMACEUTICALS CORP	ALISKIREN/AMLODPINE(SPA 100A)FIXED COMBO

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/s/

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08/12/2010

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08/12/2010

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:	January 29, 2010
To:	Norman Stockbridge, MD, Director Division of Cardiovascular and Renal Products
Through:	Kristina C. Arnwine, PharmD, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Tselaine Jones Smith, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Tekamlo (Aliskerin and Amlodipine) Tablets, 150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg and 300 mg/10 mg
Application Type/Number:	NDA 022545
Applicant/Applicant:	Novartis Pharmaceuticals Corporation, Inc.
OSE RCM #:	2009-2182

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EXECUTIVE SUMMARY

Tekamlo is the proposed proprietary name for Aliskerin and Amlodipine Mesylate Tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. 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, DMEPA finds the proposed proprietary name Tekamlo, acceptable for this product.

If any of the proposed product characteristics as stated in this review are altered prior to submission of the NDA, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Novartis Pharmaceuticals Corporation, Inc. for an assessment of the proposed proprietary name, Tekamlo, for its promotional nature and the potential to contribute to medication errors. Novartis submitted container labels, carton and insert labeling which will be reviewed under separate cover.

1.2 PRODUCT INFORMATION

Tekamlo (Aliskerin and Amlodipine Mesylate) Tablets are indicated for the treatment of hypertension as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals and in patients not adequately controlled with monotherapy. Tekamlo may be substituted for titrated components. The recommended initial dose for Tekamlo is one 150 mg/5 mg tablet daily. The dose of Tekamlo can be titrated as needed up to a maximum of 300 mg/10 mg once daily. Tekamlo is available in four strengths, 150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg and 300 mg/10 mg. It will be supplied in 30-count and 90-count bottles and blister packages of 100.

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 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Tekamlo.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'T' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

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[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)

To identify drug names that may look similar to Tekamlo, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (seven letters), upstrokes (three, capital letter 'T', lower case 'k' and lower case 'l'), down strokes (none), cross strokes (none), and dotted letters (none). Additionally, some letters in Tekamlo 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 Tekamlo.

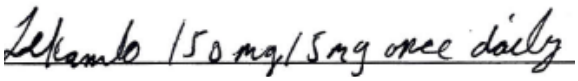
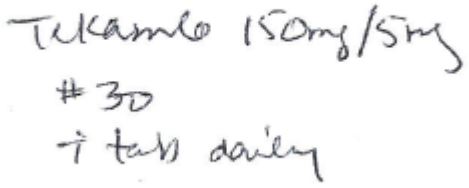
When searching to identify potential names that may sound similar to Tekamlo, the DMEPA staff searches for names with similar number of syllables (three), stresses (TEK-am-lo), tek-AM-lo or tek-am-LO) and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary. For example, 'Te-' may sound like 'Tuh-', 'k' may sound like 'ck' and '-kam' may sound like '-cam'. (See Appendix B).

The Applicant's intended pronunciation of the proprietary name is presented as TEK-AM-LO. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

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 prescription was communicated during the FDA prescription studies.

Figure 1. Tekamlo Study (conducted on November 19, 2009)

HANDWRITTEN PRESCRIPTION ORDERS	VERBAL PRESCRIPTION ORDER
Inpatient Prescription Order: 	Tekamlo 150 mg/5 mg #30 One tablet daily
Outpatient Prescription Order: 	

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of sixteen names as having some similarity to the name Tekamlo.

Fifteen of the names were thought to look like Tekamlo. These include Takadol, Tramadol, Tekturna, Tamiflu, Teladar, Fexmid, Tebamide, Tekral, Teslac, Librax, Librium, Betimol, Tubersol, Letrozole and Tikosyn. The remaining name, Tekam, was thought to look and sound like Tekamlo.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of December 16, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Tekamlo.

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

A total of 21 practitioners responded. Only five (n = 5) of the participants interpreted the name correctly as 'Tekamlo', with all of the correct interpretations occurring in the outpatient written study. None of the seven (n=7) respondents in the verbal study interpreted the name as Tekamlo.

The remainder of the written and phonetic responses misinterpreted the drug name. One respondent in the outpatient written study misinterpreted the name as 'Tekamide' which is similar to the currently marketed product, Tebamide. Respondents in the verbal study misinterpreted the name as 'Zecamlo', 'Zicamlo' and 'Zicamlo150'. Zicamlo is similar to the currently marketed product Zicam.

The remaining eight (n=8) practitioners in the inpatient written study misinterpreted the letters 'L' or 'Z' for the letter 'T' and six of the eight respondents omitted the letter 'o'. Three (n=3) of the participants in the verbal study heard the 'D-', 'S-' or 'Z-' sound instead of the 'T-' sound and all seven (n = 7) respondents misinterpreted the '-k-' sound as the hard '-c-' sound.

See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 COMMENTS FROM THE DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS (DCRP)

3.4.1 Initial Phase of Review

In response to the OSE November 24, 2009 email, the Division of Cardiovascular and Renal Products (DCRP) indicated that they did not have any comments and/or concerns with the proposed name at the initial phase of the name review.

3.4.2 Midpoint of Review

DMEPA notified the Division via e-mail that we had no objections to the proposed proprietary name, Tekamlo, on January 26, 2010. Per e-mail correspondence from the Division on January 29, 2010, they indicated they concur with our assessment of the proposed proprietary name, Tekamlo.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified four names, Teveten, Teveten HCT, Tekturna HCT and Zicam, which were thought to look similar to Tekamlo and represent a potential source of drug name confusion.

4 DISCUSSION

4.1 PROMOTIONAL REVIEW

DDMAC did not find the name Tekamlo promotional. DMEPA and the Division of Cardiovascular and Renal Products concurred with this assessment.

4.2 SAFETY REVIEW

We did not identify aspects of the name other than names with similar appearance and sound that would render the name Tekamlo objectionable.

In total, DMEPA identified 20 names as potential sources of drug name confusion with the proposed proprietary name Tekamlo.

Our evaluation determined that four (n=4) of the 20 names were eliminated from further analysis for the following reasons. Two are proprietary names that are internationally registered; one name was a drug product that is no longer marketed and has no generic equivalents available; and, one name is a homeopathic product that is unlikely to be seen on verbal and/or written orders (see Appendices D, E and F).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 16 names and lead to medication errors. This analysis determined that name similarity was unlikely to result in medication errors between Tekamlo and any of the 16 products for the reasons presented in Appendix G.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Tekamlo, is not vulnerable to name confusion that could lead to medication errors nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Tekamlo, for this product at this time.

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If the approval for this application is delayed beyond 90 days from the signature date of this review, the proposed name will be re-reviewed.

Please contact Nina Ton, OSE Project Manager, at 301-796-1486 for questions or clarifications.

5.1 COMMENTS TO THE APPLICANT

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

Tekamlo will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following re-review, we will notify you.

6 REFERENCES

1. Previous OSE Reviews

a. OSE Review 00-0297 *Teveten HCT Proprietary Name Review*

b. OSE Reviews 05-0264 and 05-0264; 2006-674 and 2007-263 *Tekturna Proprietary Name Reviews*

c. OSE Review 2007-1029 *Tekturna HCT Proprietary Name Review*

2. Micromedex Integrated Index (http://csi.micromedex.com)

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

3. 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.

4. 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.

5. 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.

6. 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.

7. 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.

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

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

9. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

10. 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.

11. 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.

12. 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.

13. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it 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.

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

USAN Stems List contains all the recognized USAN stems.

15. Red Book Pharmacy's Fundamental Reference

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

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

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

17. Medical Abbreviations Book

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

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[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.

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

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 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 Upstrokes Down strokes Cross-stokes 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, 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.

2. 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.

3. 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 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.

4. 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.

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?"***

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

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:

a. 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)].

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.

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), Joint Commission on Accreditation of Hospitals (JCOAH), 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).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Tekamlo	Scripted may appear as	Spoken may be interpreted as
T	'L', 'F', S, D	'D'
e	a, o, u, i	'-uh-', '-a-'
k	x, r, b	'-ck-', '-c-'
a	e, o, u, i	'-uh-', '-ai-', '-ay'
m	'si', 'nu', 'ru', 'su'	'-n-'
l	'b', 'i'	
o	a, e, u, i	'-uh', '-oo'
'Te-'	'Fe-', 'Fa-', 'Fu-', 'Fi-','Le-', 'La-', 'Lu-', 'Li-'	'Tuh-', 'Ta-'
'-kam'	'-xam', '-'ram', '-bam'	'-cam'

Appendix C: FDA Prescription Study Responses

Inpatient Prescription	Outpatient Prescription	Voice Prescription
Lekamb	Tekamlo	Zicamlo
Lekamb	Tekamlo	Secamlo
Lekamb	Tekamlo	Decamlo
Lekamb or Zekamb	Tekamide	Decamla
Lekamlo	Tekamlo	Zecamlo
Lekamb	Tekamlo	Tecamlo
zekamb		Zicamlo150
Lekamlo		

Appendix D: Drug products that are discontinued and no generic equivalent is available

Proprietary Name	Similarity to Tekamlo	Status
Teslac (testolactone, USP)	Look	NDA 016119 Teslac Injection withdrawn pending Federal Register notice (DAARTS) NDA 016118 Teslac Tablets no longer available in the marketplace* *Drugs at FDA, Orange Book, Clinical Pharmacology Online, Redbook 2009

Appendix E: Proprietary name used only in a foreign country

Proprietary Name	Similarity to Tekamlo	Country	Description
Tekam	Look	Europe	ketamine injection
Takadol	Look	France	tramadol

Appendix F: Products with orthographic, phonetic and/or multiple differentiating product characteristics that minimize the potential for medication errors in the usual practice settings

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tramadol tablets	Look	50 mg	One tablet orally four times a day	The eight letters in Tramadol allows it to look longer than the seven letters in Tekamlo when scripted The upstroke of the letter 'k' in the middle of the name Tekamlo helps to differentiate the name from Tramadol when scripted Although the products have numeric similarities between 50 mg and 150 mg or 5 mg even if an order for tramadol 50 mg was misinterpreted as Tekamlo 150 mg the healthcare practitioner would have to contact the prescriber to determine what strength Amlodipine Mesylate was required. Alternatively since Tekamlo has two ingredients it is less likely that a prescription is written with only the Amlodipine Mesylate strength.
Zicam Product Line Cold Remedy Cold Remedy Plus Multi-Symptom Cough Max Congestion Relief Sinus Relief Healthy Z-ssentials Allergy Relief Cold Sore	Sound	Depends on Product	Depends on Product	The 'lo' at the end of Tekamlo helps to differentiate it from Zicam when spoken Zicam are multiple over-the-counter products in a homeopathic line used to relieve cold, allergy and flu symptoms; to decrease the duration and severity of cold sores; and, to provide health and wellness with vitamins and herbal products The prescriber would have to specify the Zicam product that is desired. This information in addition to the strengths of Tekamlo would differentiate these names.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tamiflu (oseltamivir phosphate) capsule (oseltamivir phosphate) powder for suspension	Look	30 mg, 45 mg, 75 mg 12 mg/mL	Adults: 75 mg orally twice daily for 5 days Children: 15 kg – 41 kg 2 mL to 5 mL orally twice daily for 5 days	The upstroke of the letter 'k' at the beginning of the name Tekamlo helps differentiate it from the name Tamiflu when scripted The downstroke of the letter f in the name Tamiflu helps differentiate it from the name Tekamlo when scripted If an order for Tamiflu 30 mg was misinterpreted as Tekamlo 300 mg the healthcare practitioner would have to contact the prescriber to determine what strength Amlodipine Mesylate was required. Although a dose of 150 mg can be achieved with Tamiflu, since Tekamlo 150 mg is available containing two different strengths of Amlodipine Mesylate the prescriber is likely to include this information on an order. Additionally, the short duration of treatment for Tamiflu (5 days) and the maximum daily amount may also alert practitioners.
Fexmid (cyclobenzaprine hydrochloride) tablets	Look	7.5 mg	7.5 mg orally three times a day	The seven letters in the name Tekamlo allow it to look longer than the six letters in the name Fexmid The upstroke of the letters 'k' and 'l' in Tekamlo helps differentiate it from the name Fexmid when scripted The products do not have overlapping or achievable strengths (150 mg/5 mg, 50 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 7.5 mg). Although the dose of 'one tablet' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tekral (diphenhydramine and pseudoephedrine) tablets	Look	100 mg/ 120 mg	One tablet orally twice a day	The seven letters in the name Tekamlo allows it to look longer than the six letters in the name Tekral The ending letter '-o' in Tekamlo differentiates it from the name Tekral when scripted The products do not have overlapping or achievable strengths (150 mg/5 mg, 50 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 100 mg/120 mg). Although the dose of 'one tablet' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed.
Librax (chlordiazepoxide and clidinium) capsules	Look	5 mg/2.5 mg	One to two capsules orally three to four times a day	Tekamlo has two upstrokes which differentiates it from the name Librax when scripted The ending letters ('-lo') in the name Tekamlo differentiates it from the name Librax when scripted The products do not have overlapping or achievable strengths (150 mg/5 mg, 50 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 5 mg/2.5 mg). Although the dose of 'one tablet' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed. Frequency of administration (once daily vs. three to four times a day)

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Librium (chlordiazepoxide HCl) capsule	Look	5 mg, 10 mg, 25 mg	5 mg to 25 mg orally two to four times daily	Tekamlo has two upstrokes which differentiates it from the name Librium when scripted The ending letters (‘-lo’) in the name Tekamlo differentiates it from the name Librium when scripted While there is numeric overlap (5 mg or 10 mg) in the amlodipine strength of Tekamlo and strengths Librium, Tekamlo is a combination product and the strengths of both active ingredients (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg) would likely be included in an order.
Letrozole tablets (Brand Name: Femara)	Look	2.5 mg	One tablet orally once a day	The two names are differentiated if the letter ‘z’ in the name Letrozole is written with a downstroke While a dose of 5 mg could be achieved with letrozole and overlap with the amlodipine strength (5 mg) of Tekamlo, Tekamlo is a combination product and the strengths of both active ingredients (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg) would have to be known before the product can be dispensed. Alternatively since Tekamlo has two ingredients it is less likely that a prescription is written with only the Amlodipine Mesylate strength.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tikosyn (difetilide) capsules	Look	0.125 mg 0.25 mg 0.5 mg	0.5 mg orally twice a day	The upstroke of the letter 'l' at the end of the name Tekamlo differentiates it from the downstroke of the letter 'y' at the end of the name Tikosyn While there is numeric similarity in the amlodipine strength of Tekamlo (5 mg) and the 0.5 mg strength of Tikosyn, Tekamlo is a combination product and the strengths of both active ingredients (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg) would have to be known before the product can be dispensed. Alternatively, an order for Tekamlo would likely have the strength of both ingredients and not solely the Amlodipine Mesylate strength.
Teladar* (betamethasone dipropionate) cream *Teladar is no longer on the market. However, generic products are available in the marketplace.	Look	0.05%	Apply a thin film topically to the affected skin areas once or twice daily	The ending letters ('-mlo' vs. '-dar') differentiate the two names when scripted Dose (one tablet vs. sufficient amount) Dosage Form (tablet vs. cream) Route of administration (oral vs. topical) The products do not have overlapping or achievable strengths (150 mg/5 mg, 50 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 0.05%). Although the dose of '*one* tablet vs. *one* application' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tebamide (trimethobenzamide HCl) suppository	Look	200 mg	One suppository rectally three to four times a day	The eight letters of Tebamide allows it to look longer than the seven letters of Tekamlo when scripted Route of administration (oral vs. rectal) Dosage Form (tablet vs. suppository) Frequency of administration (once daily vs. three to four times a day) The products do not have overlapping or achievable strengths (150 mg/5 mg, 50 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 200 mg). Although the dose of '*one* tablet vs. *one* suppository' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed.
Betimol (timolol) ophthalmic solution	Look	0.25%	One drop in the affected eye(s) twice a day	Dosage Form (tablet vs. solution) Route of administration (oral vs. ocular) The products do not have overlapping or achievable strengths (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg vs. 0.25%). Although the dose of '*one* tablet vs. *one* drop' could overlap, the strength of Tekamlo would have to be known before the product can be dispensed.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tubersol (tuberculin purified protein derivative) injection	Look	5 tuberculin units/0.1 mL	0.1 mL intradermally into the inner surface of the forearm	The eight letters of Tubersol allows it to look longer than the seven letters of Tekamlo when scripted The letter '-o' at the end of Tekamlo differentiates it from Tubersol when scripted Dosage Form (tablet vs. injection) Route of administration (oral vs. intradermal) Frequency of administration (once daily vs. one time) Although both products share the numeral 5 in their strengths, Tekamlo is a combination product and the strengths of both active ingredients (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg) would have to be known before the product can be dispensed. Alternatively since Tekamlo has two ingredients it is less likely that a prescription is written with only the Amlodipine Mesylate strength.
Tekturna (aliskerin hemifumurate) tablets	Look	150 mg 300 mg	One tablet orally once daily	The eight letters of Tekturna allows it to look longer than the seven letters of Tekamlo when scripted The upstroke of the letter '-l-'at the end of Tekamlo differentiates it from the name Tekturna when scripted Although there is an overlap in the aliskerin strengths (150 mg or 300 mg), Tekamlo is a combination product and the strengths of both active ingredients (150 mg/5 mg, 150 mg/10 mg, 300 mg/5 mg or 300 mg/10 mg) would have to be known before the product can be dispensed.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Tekturna HCT (aliskerin hemifumurate and hydrochlorothiazide) tablets	Look	150 mg/ 12.5 mg 150 mg/25 mg 300 mg/ 12.5 mg 300 mg/25 mg	One tablet orally once daily	The upstroke of the letter '-l-'at the end of Tekamlo differentiates it from the root name Tekturna when scripted The 'HCT' modifier at the end of the name Tekturna HCT allows it to look longer than the name Tekamlo when scripted Tekamlo and Tekturna HCT are combination products that overlap in their strengths of aliskerin (150 mg and 300 mg). However, when considering the strengths of both active ingredients for the both products, these strengths cannot be achieved if Tekturna HCT was mistaken for Tekamlo and vice-a-versa.
Teveten (eprosartan mesylate) tablets	Look	400 mg (unscored) 600 mg (unscored)	400 mg to 800 mg orally once or twice daily	Tekamlo looks longer than Teveten when scripted The upstroke of the letter '-k-' in the third position of Tekamlo differentiates it from the root name Teveten when scripted If an order for Teveten 600 mg was confused as Tekamlo 600 mg the prescriber would have to call to clarify the Amlodipine Mesylate strength. Even though the maximum dose of Tekamlo is 300 mg/10 mg per day, if an order was written for Tekamlo 600 mg it would likely be written with the corresponding amount of Amlodipine Mesylate (10 mg or 20 mg) thus alerting the healthcare practitioner that it is not Teveten.

Product name with potential for confusion	Similarity to Tekamlo	Strength	Usual Signa (if applicable)	Differentiating Product Characteristics
Tekamlo **(aliskerin and amlodipine mesylate) tablets**		150 mg/5 mg 150 mg/10 mg 300 mg/5 mg 300 mg/10 mg	One tablet orally once daily. Maximum 300 mg/10 mg	
Teveten HCT (Eprosartan mesylate and hydrochlorothiazide) tablets	Look	600 mg/ 12.5 mg (unscored) 600 mg/25 mg (unscored)	One tablet orally once a day	The 'HCT' modifier at the end of the name Teveten HCT allows it to look longer than the name Tekamlo when scripted The upstroke of the letter '-k-' in the third position of Tekamlo differentiates it from Teveten when scripted Tekamlo and Teveten HCT are both combination products and doses of 600 mg can be achieved with the aliskerin portion of Tekamlo. However, the remaining active ingredient amount does not overlap between Teveten HCT and Tekamlo. Additionally, the strengths of the hydrochlorothiazide and Amlodipine Mesylate ingredient cannot be achieved if Teveten HCT was mistaken for Tekamlo and vice-a-versa.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22545	ORIG-1	NOVARTIS PHARMACEUTICALS CORP	ALISKIREN/AMLODPINE(SPA 100A)FIXED COMBO

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