CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	October 7, 2010
Application Type/Number:	NDA 022560
Through:	Zachary Oleszczuk, PharmD, Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Cathy A. Miller, MPH, BSN, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Atelvia (Risedronate Sodium) Delayed-release Tablets 35 mg
Applicant/Sponsor:	Warner Chilcott
OSE RCM #:	2010-2116

1 INTRODUCTION

This re-assessment of the proprietary name is written in response to the anticipated approval of NDA 022560 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Atelvia, acceptable in OSE Reviews #2010-808 dated June 21, 2010. The Division of Reproductive and Urologic Drug Products did not have any concerns with the proposed name, Atelvia, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective on April 23, 2010.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria previously used in OSE Reviews #2010-808. Since the time of our last proprietary name review, the dosage and administration for Atelvia has been slightly altered. Previously, the proposed dosing was (b) (4) The final dosage and administration for Atelvia has been altered to "35 mg in the morning immediately following breakfast once weekly," however, this slight alteration in dosing does not change DMEPA's evaluation of look-alike or sound-alike names identified in OSE Review #2010-808 and therefore, we did not re-evaluate previous names of concern. Additionally, DMEPA searches the United States Adopted Names (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[1] (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases in Section 4 yield six additional names thought to look like Atelvia. These names are: Abstral***, (b) (4)

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, Atelvia, as of October 5, 2010.

Our failure mode and effects analysis (FMEA) analysis determined that the name similarity between Atelvia and the six identified names was unlikely to result in medication error for the reasons presented in Appendix A.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Atelvia, 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 has no objection to the proprietary name, Atelvia, for this product at this time.

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

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

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 Metabolism and Endocrinology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE review # 2010-808 dated June 21, 2010. Proprietary Name Review of Atelvia. Miller, Cathy.

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. 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.

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

USAN Stems List contains all the recognized USAN stems.

5. CDER Proposed Name List

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis (DMEPA) for review. The list is updated weekly and maintained by DMEPA.

APPENDICES

Appendix A: Potentially confusing names with orthographic and multiple differentiating product characteristics that decrease risk of medication errors.

Proposed name: **Atelvia** **(Risedronate Sodium) Delayed-release tablet**	**Strength:** **35 mg**	**Usual dose:** **Take one tablet once weekly immediately following breakfast with at least four ounces of water. Do not lie down for thirty minutes after administration.**
Failure Mode: Name confusion	**Causes:**	**Prevention of Failure Mode:**
Abstral[***] Fentanyl Citrate Oral Disintegrating Tablets Strength: 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg and 800 mcg. Dose: 100 mcg to 800 mcg; may repeat; wait at least two hours after treating pain before taking another dose. ***Proposed name for NDA 0225210 currently under review	**Orthographic similarities:** Both names begin with the letter 'A'; the second upstroke letter 'b' can appear like the second upstroke letter 't'; and the fourth upstroke letter 't' in Abstral can appear like the fourth upstroke letter 'l' in Atelvia. **Overlapping product characteristics:** Oral table dosage form Oral route of administration	Orthographic differences in conjunction with variations in dose and frequency of administration minimize the potential for confusion. Orthographic differences: The endings of the names appear differently, 'al' versus 'ia' which provide orthographic distinction when scripted. Differentiating product characteristics: Abstral is available in six strengths with a frequency of administration schedule that varies according to pain. Atelvia is available in only one strength with a once weekly. These differentiating product characteristics would likely prompt practitioners to verify the intended order if name confusion occurred.

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

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/s/

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10/07/2010

ZACHARY A OLESZCZUK
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DENISE P TOYER
10/07/2010

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:	June 21, 2010
To:	Scott Monroe, MD, Director Division of Reproductive and Urologic Drug Products
Through:	Zachary Oleszczuk, PharmD, Acting Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Cathy A. Miller, MPH, BSN, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Atelvia (Risedronate Sodium) Delayed-release Tablets 35 mg
Application Type/Number:	NDA 022560
Applicant:	Warner Chilcott
OSE RCM #:	2010-808

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CONTENTS

EXECUTIVE SUMMARY

This review summarizes the proprietary name analysis for Atelvia (Risedronate Sodium) Delayed-release tablets. 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, the Division of Medication Error Prevention and Analysis (DMEPA) finds the proposed proprietary name, Atelvia, acceptable for this product.

1 BACKGROUND

1.1 INTRODUCTION

This review responds to a request from Warner Chilcott dated April 9, 2010 for an assessment of the proposed proprietary name, Atelvia, regarding promotional concerns and potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted container labels and carton labeling which will be reviewed separately in the forthcoming OSE Review, #2009-2049.

1.2 REGULATORY HISTORY

On April 7, 2009, the Applicant submitted a request for review of the proposed name (b) (4) under Investigational New Drug Application (IND 074086). Both the Division of Reproductive and Urologic Products (DRUP) and the Division of Medication Error and Prevention Analysis (DMEPA) had concerns about the Applicant's proposed (b) (4)

(b) (4)

(b) (4)

(b) (4)

On April 9, 2010, the Applicant submitted a request for the review of the proposed proprietary name, Atelvia.

1.3 PRODUCT INFORMATION

Actonel (Risedronate Sodium) is currently approved in an immediate release formulation tablet in 5 mg, 30 mg, 35 mg and 150 mg strengths. The 75 mg strength was previously marketed but was discontinued in June 2009. Actonel With Calcium (Risedronate Sodium and Calcium Carbonate) is currently approved in an immediate release formulation in 35 mg (Risedronate Sodium) and 1250 mg (Calcium Carbonate) strength tablets. Actonel and Actonel With Calcium are indicated for the treatment and prevention of Postmenopausal Osteoporosis. Actonel is additionally indicated for the treatment to increase bone mass in men with Osteoporosis, treatment and prevention of Glucocorticoid-induced osteoporosis, and the treatment of Paget's disease. The recommended dose for Actonel and Actonel With Calcium varies according to indication and is presented in Table 1 below. Both Actonel and Actonel With Calcium must be taken with plain water (6 to 8 ounces) at least thirty minutes before the first food or drink of the day and patients cannot lie down for thirty minutes.

Atelvia (Risedronate Sodium) Delayed-release 35 mg tablets are proposed for the indication of treatment (b) (4) of postmenopausal osteoporosis. (b) (4)

Dosing for (b) (4) 35 mg is one tablet once weekly administered immediately after breakfast.

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, Atelvia.

2.1 SEARCH CRITERIA

For this review, particular consideration is given to drug names beginning with the letter 'A' 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]

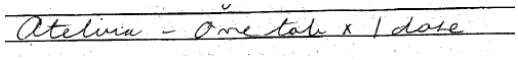
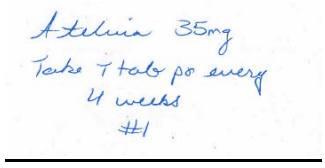
To identify drug names that may look similar to Atelvia, the DMEPA staff considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (three, capital letter 'A', lower case 't', and lowercase letter 'l'), down strokes (none), cross strokes (one lower case letter 't'), and dotted letters (one lower case letter 'i'). Additionally, several letters in Atelvia may be vulnerable to ambiguity when scripted (see Appendix B). As such, DMEPA considers these appearances when evaluating a drug name.

When searching to identify potential names that may sound similar to Atelvia, the DMEPA staff searches for names with similar number of syllables (four), stresses (A-tel-vi-a, a-TEL-v-a, a-tel-VI-a and a-tel-vi-A) and placement of vowel and consonant sounds. The Applicant did not provide an intended pronunciation of the name Atelvia with their submission. Additionally, several letters in Atelvia may be vulnerable to ambiguity when spoken and names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered

2.2 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: Atelvia Study (conducted on April 29, 2010)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order : 	Atelvia 35 mg Take one tablet once a month
Outpatient prescription: 	

[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)

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, 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 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 assessment differs, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The DMEPA searches yielded a total of 32 names as having some similarity to the name Atelvia.

Thirty of the names were thought to look like Atelvia by DMEPA. These names include Abelcet, Abreva, Activase, Activella, Adalat, Adefovir Dipivoxil, Afluria, Aldara, Aldex, Aliclen, Alinia, Altinac, Alodox, Altace, Altabax, Anexsia, Aredia, Astelin, Atabex EC, Atacand, Ativan, Atolone, Atralin, Atridox, Atripla, Celebrex, Stalevo, Stelara, Stevia, and Ultiva. The remaining two names (Del-Vi-A and Atenolol) were thought to look and sound like Atelvia by DMEPA.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 1, 2010.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA (See Section 3.1 above) and had no additional comments.

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 34 practitioners responded with none of the study participants identify existing drug products in their responses. Seventeen of the 34 participants correctly interpreted the drug name as 'Atelvia' with correct interpretations occurring more frequently in the written prescription study. The remaining written responses misinterpreted the drug name. Frequent misinterpretations in the written studies included the letters 'lvia' being misinterpreted as 'livia', 'lina' or 'luia'. Frequent misinterpretations in the oral studies

included ‘At’ being misinterpreted as ‘Ac’, ‘Ak’ or ‘Aq’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

The proposed name risk assessment submitted by the Sponsor and conducted by the (b) (4) found the name acceptable. (b) (4) identified and evaluated a total of 92 drug names that were thought to have some potential for confusion with the name Atelvia. Two of these names (Actemra and Extavia) were previously identified in the DMEPA staff searches.

Of the remaining 90 names submitted by (b) (4) three names (Adcirca, Asclera and Oleptro) were deemed to have orthographic and/or phonetic similarity to Atelvia, and thus determined to present some risk of confusion and were added to the safety evaluator risk assessment. The remaining 87 names were found to lack significant orthographic or phonetic similarity to the proposed name, Atelvia, and were not considered further. (See Appendix G for a complete list of (b) (4) names)

3.5 COMMENTS FROM THE DIVISION OF REPRODUCTIVE AND UROLOGIC PRODUCTS (DRUP)

3.5.1 Initial Phase of Review

In response to the OSE April 23, 2010 e-mail, Division of Reproductive and Urologic Products (DRUP) commented that they had no comments or objections to the proposed proprietary name, Atelvia, at the initial phase of the name review.

3.5.2 Midpoint of Review

On June 9, 2010, DMEPA notified the Division of Reproductive and Urologic Products (DRUP) via e-mail that we had no objections to the proposed proprietary name, Atelvia. Per e-mail correspondence from DRUP on June 18, 2010, they indicated that they had no concerns or comments regarding the proposed proprietary name, Atelvia.

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in the identification of seven additional names which were thought to look similar to Atelvia and represent a potential source of drug name confusion. The names identified to have look-alike similarities include Actemra, Acticin, Alfenta, Alimta, Arixtra, Avelox, and Extavia.

Thus, in total, 42 names were identified as having similarity to Atelvia. Seven names were identified by the primary safety evaluator; 32 names were identified in Section 3.1 above and three names were identified by the external name study.

4 DISCUSSION

This proposed proprietary name, Atelvia, was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. Furthermore, input from pertinent disciplines involved with the review of this application is considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed proprietary name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Reproductive and Urologic Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated 42 names for their potential similarity to the proposed proprietary name, Atelvia. Five of the 42 names were eliminated for the following reasons: one name lacked orthographic similarity, one name was found to be a discontinued product with no generics available, one was found to have limited information in commonly used databases, one of the names was found to be a foreign drug and one was found to be a sugar extract and not a drug product. (See Appendices D for details).

Failure mode and effects analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 37 names and lead to medication errors. This analysis determined that the name similarity between Atelvia and all of the 37 names was unlikely to result in medication error for the reasons presented in Appendices E and F.

Additionally, no other aspects of the name were identified as a source of confusion.

5 CONCLUSIONS AND RECOMMENDATIONS

The findings of the Proprietary Name Risk Assessment findings indicate that the proposed name, Atelvia, 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, Atelvia, for this product at this time.

If you have further questions or need clarifications, please contact Maria Wasilik, OSE Project Manager, at 301-796-0567.

6 COMMENTS TO THE APPLICANT

6.1 PROPRIETARY NAME

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

7 REFERENCES

Previous OSE Reviews:

Miller, C.A., OSE Review #2009-2224 Proprietary Name Review for (b) (4) dated April 9, 2010.

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

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

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

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

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

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

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

7. 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.

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

USPTO provides information regarding patent and trademarks.

9. 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.

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 trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. 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.

12. 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.

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. 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

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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.

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.

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

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, 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/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.

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:

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

"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:

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), 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: Letters with possible orthographic or phonetic misinterpretation

Letters in Name Atelvia	Scripted may appear as	Spoken may be interpreted as
Capital 'A'	O, N	An vowel sound
lower case 't'	i, l	'q' or 'k' sound
lower case 'e'	i, l, r	any vowel sound
lower case 'l'	e, l, i	
lower case 'v'	u, r, n	'b' sound
lower case 'i'	r, l, t	'ee' sound
lower case 'a'	o	'ya' sound, any vowel sound

Appendix C: FDA Prescription Study Responses (n=34)

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Atelina	Atelina	Acalvia
Atelivia	Atelina	Akelvia
Atelivia	Ateluia	Akelvia
Atelivia	Ateluia	Aquelvia
Atelivia	Ateluia	Atelvia
Atelvia	Ateluia	Atelvia
Atelvia	Ateluria	Atelvia
Atelvia	Atelvia	Atelvia
Atelvia	Atelvia	Atelzia
Atelvia	Atelvia	
Atelvia	Atelvia	
Atelvia		
Atelvia		
Atelvia		

Appendix D: **Names Not Considered Further For Reasons Listed**

Proprietary Name	Similarity to Atelvia	Reason/Comments
Adefovir Dipivoxil	Look-Alike	Found to lack orthographic similarity to Atelvia
Asclera	(b) (4)	Foreign Drug manufactured only in Germany. Not approved for use in the United States
Atolone	Look-Alike	Limited information found in commonly used databases. After contacting the manufacturer listed in Micromedex for 'Atolone' we found that only the generic 'Triamcinolone is distributed.
Del-Vi-A	Look and Sound-Alike	All brand and generics Vitamin A capsules discontinued
Stevia	Look-Alike	Sugar Extract / Herb (Asteraceae) – Not a drug

Appendix E: Risk of name confusion minimized by preventions/differentiated product characteristics listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of Name Confusion prevented by stated product characteristics and/or orthographic and/or phonetic differences
Atelvia **Risedronate Sodium Delayed-release tablet**		**35 mg**	(b) (4)	
Abelcet **Amphotericin B Lipid Complex** *Orthographic similarities include both names begin with the letter 'A', the letter 'b' can appear like the letter 't' and both names have the letter 'l' similarly placed*	Look Alike	100 mg/20 mL 5 mg/mL	3 mg/kg/day to 6 mg/kg/day given as intravenous infusion.	Orthographic differences include Abelcet has a cross-stroke letter 't' in the last letter position not present in Atelvia. One strength versus multiple strengths Dosage form: Injection versus tablet Route of administration: Intravenous versus oral Dose: 3 mg/kg/day to 6 mg/kg/day versus take one or take 35 mg

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of Name Confusion prevented by stated product characteristics and/or orthographic and/or phonetic differences
Atelvia **Risedronate Sodium Delayed-release tablet**		**35 mg**	(b) (4)	
Abreva Docosanol *Orthographic similarities include both names begin with the capital letter 'A' and the letter 'b' can appear like the letter 't' when scripted; both names end with the letter 'a'.* *Both products are available in only one strength*	Look-Alike	10%	Apply to affected area five times daily	No numeric overlap in strength Dosage form: Topical cream versus tablet Route of administration: Topical versus oral Dose: 'Apply' versus take one or '35 mg' Frequency: Five times daily versus once weekly
Actemra (Tocilizumab) *Orthographic similarities include both names begin with the letter 'A' , have an upstroke cross-stroke letter 't' similarly placed and end with the letter 'a'.*	Look-Alike	80 mg/4 mL 200 mg/10 mL 400 mg/20 mL	4 mg/kg to 8 mg/kg based on clinical response via intravenous infusion	Orthographic differences include an upstroke letter 'l' in the third from the last letter position of Atelvia that is not present in Actemra. One strength versus multiple strengths Dosage form: Injection versus tablet Dose: '4 mg/kg to 8 mg/kg' versus 'take one' or '35 mg' Frequency: Continuous infusion versus once weekly Route of administration: Intravenous versus oral

Acticin (Permethrin) *Orthographic similarities include both names begin with the letter 'A' and have the upstroke/ cross-stroke letter 't' in a similar letter position; both names have a dotted letter 'i' in the second from the last letter position.* *Both products are available in only one strength*	Look-Alike	5%	Massage into skin from head to feet; wash off after six to fourteen hours.	No numeric overlap in strength Dosage form: Topical cream versus tablet Dose: 'Massage into skin' versus 'take one' or '35 mg' Frequency: One application versus once weekly Route of administration: Topical versus oral
Activase Alteplace *Orthographic similarities include both names begin with the letter 'A' and have the letters 't' and 'v' similarly placed in the names.*	Look-Alike	50 mg/vial 100 mg/vial	100 mg fifteen minute bolus followed by 50 mg infusion for > 67 kg patients 15 mg bolus followed by 0.75 mg/kg infusion for patients less than 67 kg.	Orthographic differences include Activase appears longer when scripted with eight letters than Atelvia which has only seven letters. One strength versus multiple strengths Dosage form: Injection versus tablet Strength: Multiple strengths versus one strength Route of administration: Intravenous versus oral Frequency: Bolus or infusion versus take one weekly Strength: Multiple strengths versus one strength

Afluria (Influenza Virus Vaccine) *Orthographic similarities: Both names begin with the letter 'A', the letter 'f' can appear like the letter 't' when scripted and both names end with the letters 'ia'.* *Both products are available in only one strength*	Look-Alike	15 mcg/0.5 mL	Administer 0.5 mL via intramuscular injection	Dosage form: Injection versus tablet Route of administration: IM versus oral Dose: '0.5 mL' versus 'take one' or '35 mg' Frequency: One injection versus once weekly
Aldara (Imiquimod) *Orthographic similarities: Both names begin with the letter 'A'; the letter 'l' can appear like a letter 't' when scripted and the ending 'ra' can appear like 'ia' when scripted.* *Both products are available in only one strength*	Look-Alike	5%	Apply to affected area two or three times weekly for sixteen weeks; or fives times weekly for six weeks.	No numeric overlap in strength Dosage form: Topical cream versus tablet Dose: Apply to affected area versus take one or 35 mg Route of administration: Topical versus oral

Alfenta (Alfentanil Hydrochloride) *Orthographic similarities include both names begin with the letter 'A'; the upstroke letter 'l' can appear like a 't' when scripted and both names end witht the letter 'a'.* *Both products are available in only one strength.*	Look-Alike	500 mcg/mL	Adjusted to desired sedation: 3 mcg/kg to 145 mcg/kg via intravenous infusion	Orthographic differences include Alfenta has two upstroke letters 'l' and 'f' after the capital letter 'A' while Atelvia has only one upstroke letter/cross-stroke letter 't' following the capital letter 'A'. The endings also vary with a upstroke/cross-stroke letter 't' in the second to last letter position of Alfenta versus a dotted letter 'i' in Atelvia. No numeric overlap in strength Dosage form: Injection versus tablet Route of administration: Intravenous versus oral Frequency: Intermittent infusion versus once weekly
Aliclen (Salycylic Acid) *Orthographic similarities include both names begin with the letter 'A'; the upstroke letter 'l' can appear like the letter 't' and both names have an upstroke letter 'l' similarly placed.* *Both products are available in only one strength*	Look-alike	6%	Apply shampoo to scalp; work into lather and rinse; use as often as directed by physician	No numeric overlap in strength Dosage form: Topical liquid versus tablet Dose: 'Apply' versus 'take one' or '35 mg' Route of administration: Topical versus oral Frequency: Varies versus once a week
Alimta (Pemetrexed Disodium) *Orthographic similarities include both names begin with the letter 'A'; both names end in the letter 'a'.*	Look-Alike	100 mg per vial 500 mg per vial	500 mg/m^2 over ten minutes day one of twenty-one day treatment cycle	No numeric overlap in strength Dosage form: Lyophilized powder for injection versus tablet Dose: 'mg/m^2' versus 'take one' or '35 mg' Strength: Multiple strengths versus one strength Route of administration: Intravenous versus oral Frequency: 'X' day of treatment cycle versus once weekly

Altabax (Retapamulin) *Orthographic similarities include both names begin with the letter 'A'; the upstroke/cross-stroke letter 't' appears in similar letter positions of both names, and the upstroke letter 'b' can appear like an upstroke letter 'l' when scripted.* *Both products are available in only one strength.*	Look-Alike	1%	Apply a thin layer to the affected area twice daily for five days	Orthographic differences are provided by the upstroke letter 'l' that appears before the upstroke letter 't' in Altabax, which does not appear in Atelvia, and the last letter 'x' in Altabax which appears different than the last letter 'a' in Atelvia when scripted. No numeric overlap in strength Dosage form: Topical ointment versus tablet Dose: 'Apply thin layer' versus 'take one' or '35 mg' Route of administration: Topical versus oral Frequency: Twice daily versus once weekly
Altinac (Tretinoin) *Orthographic similarities include both names begin with the letter 'A' and have an upstroke/cross-stroke letter 't' similarly placed.*	Look-Alike	0.1%, 0.5%, 0.025%	Apply to area of skin at bedtime	Orthographic differences are provided by the upstroke letter 'l' that appears before the upstroke letter 't' in Altinac, which does not appear in Atelvia. No numeric overlap in strength Dosage form: Topical cream versus tablet Dose: 'Apply to area of skin' versus 'take one' or '35 mg' Route of administration: Topical versus oral Frequency: Daily at bedtime versus weekly

Aredia (Pamidronate Disodium) *Orthographic similarities include both names begin with the letter 'A', the upstroke letter 'd' can look like an upstroke letter 'l' and they are similarly positioned, and both names end with the letters 'ia'.*	Look-Alike	30 mg/vial 90 mg/vial	60 mg to 90 mg via intravenous infusion over two to twenty-four hours	Orthographic differences are provided by the upstroke/cross-stroke letter 't' in the second letter position of Atelvia that does not appear in Aredia. One strength versus multiple strengths Dosage form: Injection versus tablet Dose: '60 mg to 90 mg' versus 'take one' or '35 mg' Strength: Multiple strength versus one strength Route of administration: Intravenous versus oral Frequency: Infusion over two to twenty-four hours versus once weekly
Arixtra (Fondaparinux Sodium) *Orthographic similarities include both names begin with the letter 'A' and end with the letter 'a'.*	Look-Alike	2.5 mg/0.5 mL 5 mg/0.4 mL 7.5 mg/0.6 mL 10 mg/0.8 mL	2.5 mg to 10 mg once daily	Orthographic differences provided by the upstroke/cross-stroke letter 't' present in the second letter position of Atelvia that is not present in Arixtra. One strength versus multiple strengths Dosage form: Injection versus tablet Dose: '2.5 mg to 10 mg' versus 'take one' or '35 mg' Strength: Multiple strengths versus one strength Route of administration: Subcutaneous versus oral Frequency: Daily versus once weekly

Astelin (Azelastine Hydrochloride) *Orthographic similarities include both names begin with the letter 'A' and have the upstroke letters 't' and 'l' similarly placed.* *Both products are available in only one strength*	Look-Alike	0.125 mg/spray	One to two sprays per nostril twice daily	No numeric overlap in strength Dosage form: Topical nasal spray versus tablet Dose: 'One to two sprays' versus 'one tablet' or '35 mg' Route of administration: Topical nasally versus oral Frequency: Twice daily versus once weekly
Atenolol (Atenolol) *Orthographic similarities include both names begin with the letters 'Ate.'* *Phonetic similarities include the 'Ate' sound in the first syllable of both names.*	Look- and Sound-Alike	25 mg, 50 mg and 100 mg tablets 5 mg/10 mL injection	Tablet: 25 mg to 100 mg once daily Injection: 5 mg over five minutes followed by 5 mg over ten minutes	Orthographic differences provided by the endings of the names, 'nolol' versus 'lvia'. Phonetic differences provided by Atenolol has four syllables with the 'lol' sound in the last syllable while Atelvia has only three syllables with the 'via' sound in the last syllable. One strength versus multiple strengths Dose: '25 mg to 100 mg or 5 mg infusion' versus 'take one' or '35 mg' Strength: Multiple strengths versus one strength Dosage form: Tablet and Injection versus tablet only Frequency: Once daily or variable infusion versus once weekly
Atralin (Tretinoin) *Orthographic similarities include both names begin with the letters 'At' and have the upstroke letter 'l' and the dotted letter 'i' similarly placed.* *Both products are available in only one strength.*	Look-Alike	0.05%	Apply once daily before bedtime	No numeric overlap in strength Dose: 'Apply' versus 'take one' or '35 mg' Dosage form: Topical gel versus tablet Route of administration: Topical versus oral Frequency: Once daily versus weekly

Atridox (Doxycycline Hyclate) *Orthographic similarities include both names begin with the letters 'At' and the upstroke letter 'd' can appear like the upstroke letter 'l' and they are similarly placed.* *Both products are available in only one strength.*	Look-Alike	50 mg/syringe with Atrigel Delivery System	Administer into periodontal pocket until the formulation reaches the top of the gingival margin.	Orthographic differences provided by the endings in the names 'ox' which includes a cross-stroke 'x' versus 'ia' which includes a dotted 'i', providing distinction when scripted. No numeric overlap in strength Dosage form: Injection gel versus tablet Dosage: 'Administer certain amount' versus 'take one' or '35 mg' Frequency: During select procedure versus weekly Route of administration: Topical versus oral
Extavia (Interferon Beta-1b) *Orthographic similarities include the capital letter 'S' can appear like a capital letter 'A' when scripted and both names have the combines letters 'tel' in the names with the letter 'a' at the end of the names.* *Both products are available in only one strength*	Look-Alike	0.3 mg/vial	0.25 mg every other day	Orthographic differences are provided by variations in the beginnings of the names 'Ex' versus 'At'. No numeric overlap in strength Dosage form: Injection versus tablet Dose: 0.25 mg versus 'take one' or '35 mg' Frequency: Every other day versus once weekly Route of administration: Subcutaneous injection versus oral
Stelara (Ustekinumab) *Orthographic similarities include both names have the upstroke/cross-stroke letter 't' in the second letter position, have the upstroke letter 'l' similarly placed and end with the letter 'a'.*	Look-Alike	45 mg/0.5 mL 90 mg/1 mL	45 mg to 90 mg initial dose followed by 45 mg to 90 mg in four weeks followed again in twelve weeks	One strength versus multiple strengths Dosage form: Injection versus tablet Dose: '45 mg to 90 mg' versus 'take one or '35 mg' Strength: Multiple strengths versus one strength Frequency: Varying increments over four to twelve weeks versus once weekly Route of administration: Subcutaneous injection versus oral

Ultiva (Remifentanil Hydrochloride) *Orthographic similarities include the capital letter 'A' can appear like a capital letter 'U' when scripted; both names have the upstroke cross-stroke letter 't' similarly placed and end with the letter 'a'.*	Look-Alike	1 mg/3 mL vial 2 mg/5 mL vial 5 mg/10 mL vial	0.05 mg/kg to 2 mg/kg/min continuous infusion	One strength versus multiple strengths Dosage form: Lyophilized powder for injection versus tablet Route of administration: Intravenous infusion versus oral Frequency: Continuous infusion versus once weekly Strength: Multiple strengths versus one strength Administration: By a trained healthcare professional versus self-administration by patient

Appendix F: Risk of medication errors due to similar dosage forms, dose or strength minimized by dissimilarity of the names and/or other distinguishing product characteristics.

Proposed name: **Atelvia** **Risedronate Sodium Delayed-release tablet**	**Strength:** **35 mg** **(Strength may be omitted during prescribing and procurement steps of medication use process for single strength products.)**	**Usual dose:** (b) (4)
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Activella (Estradiol and Norethindrone Acetate) Strength: 1 mg and 0.5 mg; 0.5 mg and 0.1 mg Dose: Take one tablet once daily	Orthographic similarity: Both names begin with the letter 'A', have the upstroke / cross-stroke letter 't' similarly placed and end with the letter 'a'. Dosage form: Tablets Route of administration: Oral Dose: Take one	Orthographic differences and variations in numeric strength, dose presentation and frequency of administration minimize the potential for confusion. *Rationale:* Activella has nine letters making it appear longer when scripted than Atelvia, which has only seven letters. The two upstroke letters 'l' positioned in the second and third from the last letter positions of the name Activella provide orthographic distinction from Atelvia. Activella is available in two strengths and therefore, would be included on prescription orders (1 mg/0.5 mg or 0.5 mg/0.1 mg) providing distinction that would differentiate the product from Atelvia. Frequency of administrations also vary (once daily versus once weekly) which would also be included on prescription orders and provide product distinction.
Adalat CC (Nifedipine) Strength: 30 mg, 60 mg and 90 mg tablets Dose: 30 mg to 90 mg once daily	Orthographic similarity: Both names begin with the letter 'A' and the upstroke letter 'd' can appear like an upstroke letter 't' when scripted. Both names have the upstroke letter 'l' similarly placed in the name. Dosage form: Tablets Route of administration: Oral	Orthographic differences and frequency of administration minimize the potential for confusion. *Rationale:* Adalat ends with an upstroke/cross-stroke letter 't' providing orthographic distinction from Atelvia, which ends with the letters 'ia'. Frequency of administrations vary (once to three times daily versus once weekly) which would also be included on prescription orders and provide product distinction that would prompt practitioners to clarify the intended order.

Adcirca (Tadalafil) Strength: 20 mg Dose: 20 mg to 40 mg once daily Dosage form: Tablet	Orthographic similarity: Both names begin with the letter 'A' and the upstroke letter 'd' can appear like an upstroke letter 'l' when scripted. Both names end with the letter 'a'. Dosage form: Tablet Single strength availability	Orthographic differences, available strengths and dosing, packaging configuration and variations in frequency of administration minimize the potential for confusion. *Rationale:* There is an upstroke letter 'l' in the fourth from the last letter position of Atelvia that is not present in Adcirca, which adds distinction and orthographic distinction when scripted. Also, the dotted letter 'i' appears in different letter positions of Adcircia versus Atelvia. Frequency of administration varies between the two products (daily versus weekly) providing distinction that would prompt practitioners to clarify the intended order. Lastly, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Adcirca (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.
Aldex (Guaifenesin and Phenylephrine) Strength: 650 mg/25 mg Dosage form: Tablet Dose: Take one tablet every four to six hours	Orthographic similarity: Both names begin with the letter 'A' and the upstroke letter 'l' can appear like the upstroke letter 't'. Dosage form: Tablet Dose: Take one Route of administration: Oral Single strength availability	Orthographic differences and variations in the packaging configuration and frequency of administration minimize the potential for confusion. *Rationale:* Aldex has five letters while Atelvia has seven letters, making the name appear longer when scripted. Aldex ends with the cross-stroke letter 'x' that provides distinction from Atelvia, which ends with the letter 'a'. Frequency of administrations vary between the two products (every four to six hours versus once weekly) providing distinction on prescription orders that would prompt practitioners to clarify the intended drug product. Additionally, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Aldex (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.

Alinia (Nitazoxanide) Strength: 500 mg tablet 100 mg/5 mL oral suspension Dosage form: Tablet and oral suspension Dose: One tablet or 5 mL every twelve hours for three days	Orthographic similarity: Both names begin with the letter 'A' and both names end with the letters 'ia'. Dose: Take one Route of administration: Oral Single Strength availability	Orthographic differences and variations in the frequency of administration minimize the potential for confusion. *Rationale:* Atelvia contains a cross-stroke 't' not contained in Alinia. Also, there upstroke letter 'l' in the fourth letter position of Atelvia that is not present in the same letter position of Alinia, providing orthographic distinction. The frequency of administrations and durations also vary (every twelve hours for three days versus one weekly) providing additional distinction on prescription orders that would prompt practitioners to clarify the intended drug product. Lastly, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Alinia (#30, #60 or 'X' mL) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.
Alodox (Doxycycline Hyclate) Strength: 20 mg Dosage form: Tablet Dose: One tablet twice daily	Orthographic similarity: Both names begin with the letter 'A', the upstroke letter 'l' can appear like an upstroke letter 't' and the upstroke letter 'd' can appear like an upstroke letter 'l' when scripted. Dose: Take one Dosage form: tablet Route of administration: Oral Single strength availability	Orthographic differences, variations in the packaging configuration and frequency of administration minimize the potential for confusion. *Rationale:* The name endings ('dox' versus 'via') appear differently when scripted providing orthographic distinction. Frequency varies between the products (twice daily versus once weekly) providing additional distinction on prescription orders that would prompt practitioners to clarify the intended drug product. Also, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Atodox (#60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.

Altace (Ramipril) Strength: 1.25 mg, 2.5 mg, 5 mg and 10 mg Dosage form: Capsule and tablets Dose: 1.25 mg to 10 mg once daily	Orthographic similarity: Both names begin with the letter 'A', the second upstroke letter 'l' can appear like an upstroke letter 't' when scripted. Achievable dose of '35 mg' Route of administration: Oral	Orthographic differences, and variations in the product packaging and frequency of administration minimize the potential for confusion. *Rationale:* There is an upstroke letter 'l' in the fourth from the last letter position of Atelvia that is not present in the same letter position of Altace providing orthographic distinction. The available strengths and the frequency of administrations vary (once daily versus once weekly) providing distinction on prescription orders that would prompt practitioners to clarify the intended drug product. Although it is possible to obtain an achievable dose of '35 mg' by combining strengths of Altace, the dose would be substantially higher than the labeled recommended dose and practitioners would likely clarify the intended dose. Also, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Altace (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.
Anexsia (Acetaminophen and Hydrocodone Bitartrate) Strength: 325 mg/5 mg, 325 mg/7.5 mg, 7.5 mg/650 mg, 500 mg/5 mg, and 750 mg/10 mg Dose: One to two tablets (325 mg/5 mg to 750 mg/ 10 mg every four to six hours for pain.	Orthographic similarity: Both names begin with the letter 'A' and end with the letters 'ia'. Route of administration: Oral	Orthographic differences, and variations in strength, dose and frequency of administration minimize the potential for confusion. *Rationale:* There is an upstroke/cross-stroke letter 't' in the second letter position and an upstroke letter 'l' in the fourth letter position of Atelvia that are not present in Anexsia, providing orthographic variation when scripted. Anexsia is available in multiple strengths and is dosing frequency ranges from every four to six hours, while Atelvia is available in only one strength and is administered once weekly. Prescription orders for Anexsia would include the strength, dose and frequency and therefore, would provide distinction that would differentiate the product from Atelvia.

Atabex EC (Prenatal Multi-vitamin) Dose: Take one tablet once daily Dosage form: Tablet	Orthographic similarity: Both names begin with the letters 'At' and the upstroke letter 'b' can appear like an upstroke letter 'l' when scripted. Dosage form: Tablet Dose: Take one Route of administration: Oral	Orthographic differences and variations in the packaging configuration, frequency of administration and patient population minimize the potential for confusion. *Rationale:* There is a cross-stroke letter 'x' in the last letter position of Atabex EC not present in Atelvia. Additionally, the modifier 'EC' provides orthographic distinction that differentiates the name from Atelvia. Frequency of administrations vary between the products (once daily versus once weekly). Additionally, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Atabex EC (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that would prompt practitioners to clarify the intended drug product.
Atacand (Candesartan Cilexitil) Strength: 4 mg, 8 mg, 16 mg and 32 mg Dose: 4 mg to 32 mg once daily Dosage form: tablet	Orthographic similarity: Both names begin with the letters 'At'. Dosage form: Tablet Route of administration: Oral	Orthographic differences, variations in the available strengths, dose and frequency of administration minimize the potential for confusion. *Rationale:* Atacand ends with an upstroke letter 'd' which is not present in Atelvia. Additionally, Atelvia contains an upstroke letter 'l' in the fourth from the last letter position that is not present in a similar letter position of Atacand. Atacand is available in multiple strengths and a '35 mg' dose is not achievable with the available strengths. The dose information would be included on prescription orders, providing distinction that would differentiate the product from Atelvia. Additionally, frequency of administrations vary between the two products (once daily versus once weekly) providing additional distinction on prescription orders that would prompt practitioners to clarify the intended drug product.

Ativan (Lorazepam) Strength: 0.5 mg, 1 mg and 2 mg Dose: 0.5 mg to 6 mg daily in divided doses Dosage form: Tablet	Orthographic similarity: Both names begin with the letters 'At', and the dotted letter 'i' can appear like the letter 'e' Dosage form: Tablet Route of administration: Oral	Orthographic differences, and variation in available strength and dose minimize the potential for confusion. *Rationale:* There is an upstroke letter 'l' in the fourth letter position and and a dotted letter 'i' in the sixth letter position of the name Atelvia that are not present in similar letter positions of the name Ativan. Ativan is available in multiple strengths and doses, which would be included on prescription order and provide distinction that would differentiate the product from Atelvia. Frequency of administrations also vary between the two products (daily divided doses versus weekly), providing additional distinction on prescription orders that would prompt practitioners to clarify the intended drug product.
Atripla (Afavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate) Strength: 600 mg/200 mg /300 mg Dose: One tablet once daily on empty stomach Dosage form: Tablet	Orthographic similarity: Both names begin with the letters 'At' and end with the letter 'a'. Dose: Take one Dosage form: Tablet form	Orthographic differences and variations in the frequency of administration minimize the potential for confusion. *Rationale*: The is a downstroke letter 'p' followed by an upstroke letter 'l' in Atripla not present in the same letter positions of the name Atelvia. The frequency of administration varies between the two products (once daily versus once weekly) and would be included on prescription orders, which would prompt practitioners to clarify the intended product. Additionally, Atelvia is supplied as a dose pack of a four-count (b) (4) package. The quantity on prescription orders would vary significantly between Atripla (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that may prompt practitioners to clarify the intended drug product.

Avelox (Moxifloxacin Hydrochloride) Strength: 400 mg tablets and 400 mg/250 mL injection Dosage form: Tablet and Injection Dose: One tablet every twenty-four hours or 400 mg infused over sixty-minutes	Orthographic similarity: Both names begin with the letter 'A', have the letter 'e' in the third letter position and have an upstroke letter 'l' in similar letter positions. Dose: One tablet Dosage form: Both available in tablet form	Orthographic differences and variations in the frequency minimize the potential for confusion. *Rationale:* There is a cross-stroke upstroke letter 't' in the second letter position of Atelvia not present in Avelox and a cross-stroke letter 'x' in the last letter position of Avelox not present in Atelvia. The presentation of the frequency of administration varies between the two products (once weekly versus once daily), providing added distinction on prescription orders that may prompt practitioners to clarify the intended product on prescription orders. Also, Atelvia is supplied as a dose pack of a four-count (b) (4) nt package. The quantity on prescription orders for the oral tablet dosage form would vary significantly between Avelox (#30 or #60) versus Atelvia ('X' number of 4-pack (b) (4) cartons) providing distinction that may prompt practitioners to clarify the intended drug product.

Celebrex (Celecoxib) Strength: 50 mg, 100 mg, 400 mg Dosage form: Capsule Dose: 50 mg to 400 mg once or twice daily	Orthographic similarity: The capital letter 'C' can appear like a capital letter 'A' and the upstroke letter 'b' can appear like an upstroke letter 'l' when scripted. Route of administration: Oral Dosage form: Tablet	Orthographic differences, variations in the available strength, dose and frequency of administration minimize confusion. *Rationale:* Celebrex appears longer when scripted with eight letters, than Atelvia, which only has seven letters. There is a cross-stroke letter 'x' in the last letter position of Celebrex that is not present in Atelvia, providing added distinction. Celebrex is available in multiple strengths and doses would be included on prescription orders and provide distinction from Atelvia, which is only available in one strength and one dose. Additionally, the frequency of administration varies between the two products (once or twice daily versus once weekly) providing added distinction that would prompt practitioners to verify the intended product on prescription orders.
Oleptro (Trazodone) Strength: 150 mg and 300 mg Dose: 150 mg to 375 mg once daily (tablets may be cut in half to achieve 75 mg dose) Dosage form: Tablet	Orthographic similarity: The capital letter 'O' can appear like a capital letter 'A', the upstroke letter 'l' can appear like an upstroke letter 't' and the last letter 'o' can appear like the letter 'a' when scripted. Route administration: Oral Dosage form: tablet	Orthographic differences, variations in the available strengths, dose and frequency of administration minimize confusion. *Rationale:* There is a downstroke letter 'p' in the fourth letter position of Oleptro that is not present in Atelvia that provides orthographic distinction. Atelvia is only available in one 35 mg strength and one dose, while Oleptro is available in two strengths and it is not possible to achieve a '35 mg' dose from the available strengths. Prescription orders would include dose information and would provide distinction that would prompt practitioners to verify the intended order. Additionally, the frequency of administration varies between the two products (daily versus weekly) provided added product distinction.
Stalevo (Carbidopa, Levodopa and Entacapone) Strength: 12.5 mg/50 mg/200 mg 75 mg/18.75 mg/75 mg 100 mg/25 mg/100 mg 125 mg/31.25 mg/125 mg 150 mg/37.5 mg/150 mg 200 mg/50 mg/200 mg Dose: 12.5 mg/50 mg/	Orthographic similarity: 'Stal' can appear like 'Atl when scripted and both names have an upstroke letter 'l' in the same letter position. Route of administration: Oral Dosage form: Tablet	Variations in available strengths, doses and frequency of administration minimize the potential for confusion. *Rationale:* Stalevo is available in multiple strengths and it is not possible to achieve a '35 mg' dose from the available doses. The dose would be included on prescription orders and provide distinction from Atelvia, which is only available in one strength and one dose. Additionally, the frequency of administration varies between the two products (daily versus once weekly) providing added distinction that would prompt practitioners to verify the intended product on prescription orders.

200 mg to 200 mg/ 50 mg/200 mg titrated 1:4 ratio of Carbidopa to Levodopa daily		

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Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22560	ORIG-1	WARNER CHILCOTT CO LLC	(b) (4)

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

/s/

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