

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and Information Sources

Our search identified 18 names as having some similarity to the name Acanya _____, Gel, Acanya Gel, or Acanya.

Twelve of the eighteen names were thought to look like Acanya/Acanya Gel/Acanya _____ Gel, which include: Atacand, Amerge, Avinza, Acacia, Acomplia^{***}, Claforan, _____ Cimzia, Albenza, Acova, Arava, and _____. The name, Arranon, was thought to sound like Acanya/Acanya Gel/Acanya _____ Gel. Additionally, five names (Avandia, Aczone, Canasa, _____ and Acanera) were thought to both look and sound like Acanya/Acanya Gel/Acanya _____ Gel.

On July 18, 2008, the name Acanya/Acanya Gel/Acanya _____ Gel was searched against the United States Adopted Names (USAN) stem list and the proposed name was found to contain no USAN stems.

3.1.2 Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by the Division of Medication Error Prevention and Analysis staff (see section 3.1.1. above), and did not note any additional names thought to have orthographic or phonetic similarity to Acanya/Acanya Gel/Acanya _____ Gel and have the potential for confusion.

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

3.1.3 CDER Prescription Analysis Studies

A total of 33 practitioners responded. About 67% of the participants (n=22) interpreted the name correctly as "Acanya", with correct interpretation occurring more frequently in the outpatient written study. The remainder of the responses (n=11) misinterpreted the drug name, with the incorrect interpretation occurring more frequently in the verbal study. In fact, all of the responses for the verbal study were incorrect (n=6)

More specifically, the most common misinterpretation in the verbal study was "Aconya" (n=3). About 71% (n=12) of the inpatient study responses were correct, with "Ucanya" (n=2) as the most common misinterpretation. Additionally, "Abanza" was a response similar to "Albenza", an approved product currently marketed in the United States that was also identified in our database and information search. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

3.1.4 Comments from the Office of New Drug Quality Assessment (ONDQA)

ONDQA determined "Gel" to be the proper dosage form designation for this product as expressed in an email dated March 3, 2008, from, Rajiv Agarwal, the chemist assigned to this application.

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3.1.5 Safety Evaluator Risk Assessment

Independent searches by the primary Safety Evaluator identified one additional name, Orenca, thought to look similar to Acanya/Acanya Gel/Acanya _____ Gel and represent a potential source of drug name confusion. As such, a total of 19 names were analyzed to determine if the drug names could be confused with Acanya/Acanya Gel/Acanya _____ Gel, and if the drug name confusion would likely result in a medication error in the usual clinical practice setting. b(4)

All of the identified names were determined to have some orthographic and/or phonetic similarity to Acanya/Acanya Gel/Acanya _____ Gel, and thus determined to present some risk for confusion. Failure mode and effects analysis (FMEA) was then applied to determine if the proposed name, Acanya/Acanya Gel/Acanya _____ Gel, could potentially be confused with any of the 19 names and lead to medication errors. b(4)

This analysis determined that the similarity between Acanya/Acanya Gel/Acanya _____ Gel and the identified names was unlikely to result in medication errors for all nineteen names for reasons described and outlined in Appendices C through I.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

The results of the Proprietary Name Risk Assessment found that the proposed name, Acanya _____ Gel, has some similarity to other proprietary and established drug names, but the findings of the FMEA indicates that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors.

However, the Applicant's proposed name "Acanya _____ Gel" was not acceptable to ONDQA. ONDQA indicated that the use of the modifier, Aqueous, is inaccurate for this product. Consequently, they will be recommending deletion of the descriptor, _____, from this proprietary name. Since DMEPA's FMEA took into consideration that this product may be prescribed as "Acanya Gel", we have no concerns with ONDQA's recommendation that _____ be deleted. b(4)

The findings of the Proprietary Name Risk Assessment are based upon current understanding of factors that contribute to medication errors involving name confusion. Although we believe the findings of the Risk Assessment to be robust, our findings do have limitations. First, because our assessment involves a limited number of practitioners, it is possible that the analysis did not identify a potentially confusing name. Also, there is some possibility that our Risk Assessment failed to consider a circumstance in which confusion could arise. However, the Division Medication Error Prevention and Analysis Staff believe that these limitations are sufficiently minimized by the use of an Expert Panel, and the CDER Prescription Studies that involved 123 CDER practitioners.

5 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Acanya _____ Gel, does not appear to be vulnerable to name confusion that could lead to medication errors. However based upon ONDQA's analysis that the descriptor " _____" is inappropriate for this dosage form, we object to the name, Acanya _____ Gel. Conversely, DMEPA does not object to the use of the proprietary name Acanya Gel. b(4)

6 RECOMMENDATIONS

6.1 COMMENTS TO THE DIVISION

The Division of Medication Error Prevention and Analysis objects to the use of the proprietary name, Acanya ~~_____~~ Gel, for this product. However, we have no objection to the use of the proprietary name, Acanya Gel, for this product. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, we rescind this Risk Assessment finding, and recommend that the name be resubmitted for review. If the product approval is delayed beyond 90 day from the date of this review, the proposed name must be resubmitted for evaluation.

b(4)

The Division of Medication Error Prevention and Analysis would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy us on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Janet Anderson, OSE Project Manager, at 301-796-0675.

7 REFERENCES

1. *Adverse Events Reporting System (AERS)*

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufacturers that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential post marketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

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

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

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

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

4. *Drug Facts and Comparisons, online version, St. Louis, MO* (<http://factsandcomparisons.com>)

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

5. *AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in 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>)

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

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

Provides information regarding patent and trademarks.

10. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

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

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)

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)

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

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

List contains all the recognized USAN stems.

15. Red Book Pharmacy's Fundamental Reference

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

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

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

17. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The medication error staff considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The medication error 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* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has lead to medication errors. The Medication error staff apply their expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (i.e. "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the medication error staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, because the Applicant has little control over how the name will be spoken in practice, DMEPA also considers a variety of pronunciations that could occur in the English language.

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	<ul style="list-style-type: none"> 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 Downstrokes Cross-strokes Dotted letters Ambiguity introduced	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication

		by scripting letters Overlapping product characteristics	
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	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Appendix B: CDER Prescription Study Responses for Acanya — Gel

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Outpatient Prescription	Voice Prescription	Inpatient Medication Order
Acanya	Aconya	Acanya
Acanya	Abanza	Acanya
Acanya	Acania	Acanya
Acanya	Aconya	Acanya
Acanya	Aconya	Ucanya
Acanya	Acconya	Ucanya
Acanya		Acanya
Acanya		Acanza
Acanya		Acanya
Acanya		Acanya (?Ucunya)
		Acoaya
		Acanya
		Accnya

Appendix C: Proprietary names lacking convincing look-alike and/or sound-alike similarities to Acanya — Gel

Proprietary Name	Similarity to Acanya — Gel
Atacand	Look
Claforan	Look
Arranon	Sound
Aczone	Look/Sound

b(4)

Appendix D: Proprietary names with minimal information available in commonly used drug references.

Name	Similarity to Acanya Gel	Relevant information
Acacia	Look	Used as a demulcent in pharmaceutical manufacturing
Anya	Look / Sound	USPTO Live trademark by Wyeth Corporation for oral contraceptives
Acanera	Look / Sound	USPTO Live trademark by Dow Pharmaceuticals for pharmaceutical products for dermatological conditions

b(4)

Appendix E: Proprietary name of a product in a foreign country

Proprietary Name	Similarity to Acanya Gel	Country	
Acomplia***	Look	Canada, Mexico, France, United Kingdom, Greece	Name rejected by DMEPA (OSE Review 04-0134), product not approvable under name "Zimulti"

b(4)

Appendix F: Proprietary names for products approved under a different name

Proprietary Name	Similarity to Acanya Gel	Status
Acova*** (NDA 20-883)	Look	Product approved under name "Argatroban"
Ecando*** (NDA 21-632)	Look	Product approved under name "Eraxis"

b(4)

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Appendix G: Proprietary names that differ in strength and usual dose:

Product name with potential for confusion	Similarity to Acanya Gel	Strength	Usual Dose
Acanya , Gel (Clindamycin Phosphate and Benzoyl Peroxide)		1.2%/2.5 %	Apply to affected area once daily or as directed
Avinza (morphine sulfate) capsules, extended release	Look	20 mg, 30 mg, 50 mg, 60 mg, 80 mg, 100 mg, 120 mg	1 capsule once every 24 hours. It is necessary to adjust the dosing regimen for each patient individually
Arava (leflunomide) tablets	Look	10 mg, 20 mg, 100 mg	100 mg orally once daily for 3 days, then 20 mg orally once daily
Avandia (rosiglitazone maleate) tablets	Look/Sound	2 mg, 4 mg, 8 mg	4 mg daily or 2 mg twice daily; maximum dose 8 mg per day

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Appendix H: Proprietary name with similar numerical strength overlap

<p>Acanya Gel (Clindamycin Phosphate and Benzoyl Peroxide)</p>	<p>1.2 %/2.5 %</p>	<p>Usual dose: Apply to affected area once daily or as directed.</p>
<p>Failure Mode: Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Effects</p>
<p>Amerge (naratriptan hydrochloride) 1 mg, 2.5 mg tablets</p>	<p>Orthographic similarity: share the first letter ('A'), downstroke in same position ('g' vs. 'y'), 'r' may appear as 'n'</p> <p>Similar numerical strengths: 2.5 mg vs. 2.5%</p>	<p>Orthographic and usual dose differences minimize the likelihood of medication errors in the normal practice settings.</p> <p><i>Rationale:</i></p> <p>Orthographic differences include the dissimilarity of the middle letters of the names ('-me-' vs. '-ca-').</p> <p>Usual dose: 1 tablet orally as needed for acute migraine. May repeat dose after 4 hours, not to exceed 5 mg/24 hours</p> <p>A medication order for Amerge may include words such as "as needed" and instructions for repeating doses. Whereas, a medication order for Acanya will likely include distinguishers such as "apply", "small amount" and "affected area".</p> <p>Since Acanya is a single strength product, the prescriber may omit the strength on a medication order. However, a product strength is necessary before Amerge may be dispensed because it is available in two strengths.</p> <p>Although the strengths of the products are numerically identical, the units of measure differ (mg vs. %).</p>

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