

### 3 RESULTS

#### 3.1 PROPRIETARY NAME RISK ASSESSMENT

##### 3.1.1 Database and Information Sources

Our search identified a total of thirty-nine (39) names as having some similarity to the name, Cetraxal.

Twenty-four (24) of the thirty-nine (39) names were thought to look like Cetraxal which include: Cetrix, Cetacort, Atralin, Atarax, Cetraxil, Cetriaf, Cortrosyn, Adapaline, Cetirizine, Letrozol, Letrozole, Cartical, cefadroxil, calcitrol, carteolol, Ciloxan, Cartil, calcitriol, Calderol, Anturo<sup>\*\*\*</sup>, Certrid<sup>\*\*\*</sup>, cetrotide, Citanest, and ~~\_\_\_\_\_~~<sup>\*\*\*</sup>. Four (4) names (tetrachel, citrical, Cipro XR, Ketaxol) were thought to sound like Cetraxal and eight (8) names (Cetraxol, citruceal, Centrax, Cetraxate, Cetriaxal, Cetraxal Plus, Cetraxal Otico and Cetraxal) were thought to look and sound similar to Cetraxal. Three (3) names (Citracal, Citruceal and Trexal) were previously identified (OSE# 05-0132 dated July 7, 2005) as names which were similar to Cetraxal and these names were again identified for this review. One exception is that although Trexal was thought to sound similar to Cetraxal in our previous review, this name was felt to look and sound similar to Cetraxal in this evaluation.

b(4)

The Division of Medication Error Prevention and Analysis did not identify any USAN stems in the name Cetraxal as of February 18, 2009.

##### 3.1.2 CDER Expert Panel Discussion

The Expert Panel reviewed the pool of names identified by DMEPA staff (see section 3.1.1. above), and noted no additional names thought to have orthographic similarity to Cetraxal 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 FDA Prescription Analysis Studies

A total of 28 practitioners responded, but none of the responses overlapped with any existing or proposed drug names. Less than half of the participants (n=12) interpreted the name correctly as "Cetraxal," with correct interpretations occurring primarily in the written studies, inpatient (n = 5) and outpatient (n = 6). In the verbal studies, only one response was correct. See Appendix B for the complete listing of interpretations from the verbal and written prescription studies.

##### 3.1.4 AERS Selection of Cases

Our search of AERS did not identify any medication errors associated with Cetraxal as of February 20, 2009.

##### 3.1.5 Safety Evaluator Risk Assessment

Independent searches by the primary safety evaluator identified an additional three names thought to look similar to Cetraxal and represent a potential source of drug name confusion. The names are: Acthrel, Actonel, and Colazal. Thus, a total of forty-two names were analyzed to determine if the drug names could be confused with Cetraxal and if the drug name confusion would likely result in a medication error.

Nineteen of the forty-two names lacked orthographic and/or phonetic similarity to Cetraxal, and were not evaluated further (Appendix C).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed name could potentially be confused with any of the remaining twenty-three (23) names and lead to medication errors. This analysis determined that the name similarity between Cetraxal and the identified names was unlikely to result in medication errors with any of the twenty-three names identified for the reasons presented in Appendices D through J.

#### **4 DISCUSSION**

Forty-two names were evaluated for their potential similarity to the proposed name, Cetraxal. The FMEA indicates that the proposed name is not likely to result in name confusion that could lead to medication errors.

#### **5 CONCLUSIONS AND RECOMMENDATIONS**

The Proprietary Name Risk Assessment findings indicate that the proposed name, Cetraxal, is not vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Cetraxal, for this product at this time. Additionally, DDMAC does not object to the proposed name, Cetraxal, from a promotional perspective. However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

##### **5.1 COMMENTS TO THE DIVISION**

We 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 the Division of Medication Error Prevention and Analysis on any correspondence to the Applicant pertaining to this review. If you have further questions or need clarifications, please contact Mariene Hammer, OSE Project Manager, at 301-796-0757.

##### **5.2 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics are altered prior to approval of the marketing application or if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

## 6 REFERENCES

1. *OSE Review# 05-0132 Proprietary Name Review for Cetraxal (Ciprofloxacin Otic Solution) 0.2%, Bridges, T.; July 7, 2005.*

2. *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 manufactures 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 postmarketing 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.

3. *Micromedex Integrated Index (<http://weblarn/>)*

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

4. *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 DMETS, FDA.

5. *Drug Facts and Comparisons, online version, St. Louis, MO (<http://weblarn/>)*

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

6. *AMF Decision Support System [DSS]*

DSS is a government database used to track individual submissions and assignments in review divisions.

7. *Division of Medication Error Prevention and Analysis proprietary name consultation requests*

This is a list of proposed and pending names that is generated by DMEPA from the Access database/tracking system.

8. *Drugs@FDA (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)*

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

**9. *Electronic online version of the FDA Orange Book***  
***(<http://www.fda.gov/cder/ob/da/aml.htm>)***

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

**10. *U.S. Patent and Trademark Office website*** ***<http://www.uspto.gov>***

Provides information regarding patent and trademarks.

**11. *Clinical Pharmacology Online*** ***(<http://weblern/>)***

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.

**12. *Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at***  
***[www.thomson-thomson.com](http://www.thomson-thomson.com)***

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and tradenames that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

**13. *Natural Medicines Comprehensive Databases*** ***(<http://weblern/>)***

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

**14. *Stat/Ref*** ***(<http://weblern/>)***

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.

**15. *United States Adopted Names website*** ***(<http://www.ama-assn.org/ama/pub/category/4782.html>)***

List contains all the recognized USAN stems.

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

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

**17. *Lexi-Comp*** ***([www.pharmacist.com](http://www.pharmacist.com))***

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

**18. *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 compares 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 led 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 compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, because the Sponsor 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"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Uptakes Downstrokes Cross-strokes	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

		<b>Dotted letters</b> <b>Ambiguity introduced by scripting letters</b> <b>Overlapping product characteristics</b>	
<b>Sound-alike</b>	<b>Phonetic similarity</b>	<b>Identical prefix</b> <b>Identical infix</b> <b>Identical suffix</b> <b>Number of syllables</b> <b>Stresses</b> <b>Placement of vowel sounds</b> <b>Placement of consonant sounds</b> <b>Overlapping product characteristics</b>	<ul style="list-style-type: none"> <li>• <b>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</b></li> </ul>

**Appendix B:**

CDER Prescription Study Responses for proposed name, Cetraxal.

Original Prescription	Voice Prescription	Important Medication Order
cetraxal	citraxel	cetraxal
cetraxal	cytraxil	cetraxal
cetraxal	sitraxel	cetraxa
cetraxal	citrakcel	cetraxal
centraxal	Visitraxil ("Originally I thought fourth prescription is Sitraxil")	cetraxal
cetraxol	cetraxil	cetraxol
cetraxal	cetraxil	cetraxal
cetraxal	sitracol	
	cetraxel	
	sitraxil	
	citrexil	
	cetraxal	
	sintraxil	

**Appendix C: Proprietary names that lack convincing sound-alike or look-alike similarities to Cetraxal.**

Proprietary Name	Similarity
Cetrix	Look
Cortrosyn	Look
Adapaline	Look
Cefadroxil	Look
Calcitrol	Look

Carteolol	Look
Ciloxan	Look
Cortil	Look
Calcitriol	Look
Calderol	Look
Cetrotide	Look
Tetrachel	Sound
Citrical	Sound
Cipro XR	Sound
Centrax	Look and Sound
Cetraxate	Look and Sound
ketaxol	Sound
Cetriaif	Look
Trexall	Look and Sound

**Appendix D:** Name which is the subject of this review and the proprietary name for ciprofloxacin (oral and otic dosage forms) in the following countries: Canada, Mexico, Ireland, Japan, South Korea, Central America, Dominican Republic, Spain, Guinea.

Proprietary Name	Similarity to Cetraxal
Cetraxal	Look and Sound

**Appendix E: Names not found in commonly referenced databases.**

<b>Proprietary Name</b>	<b>Similarity to Cetraxal</b>
Citrucal	Look and Sound

**Appendix E: Proprietary names used only in Foreign Countries**

<b>Proprietary Name</b>	<b>Similarity to Cetraxal</b>	<b>Country</b>
Cetrazil	Look	Italy (discontinued or no longer actively marketed per Micromedex database)
Cetraxal Plus (ciprofloxacin and fluocinolone) otic	Look and Sound	Spain, Central America, South Korea, Guinea and Dominican Republic
Cetrixal (cetirizine)	Look and Sound	Indonesia
Cetrasol (ascorbic acid)	Look and Sound	Philippines
Cetraxal Otic	Look and Sound	Spain (described as an 'otic anti-infective')