

**Appendix G: Products with no numerical overlap in strength and dose.**

<b>Cetrazal</b> (ciprofloxacin otic solution)		<b>Strength:</b> 0.2%	<b>Usual dose:</b> contents of one unit-dose vial (0.25 mL) instilled into the affected ear (s) twice daily for 7 days
<b>Product name with potential for confusion</b>	<b>Similarity to Proposed Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose (if applicable):</b>
<b>Atarax</b> (hydroxyzine hydrochloride) oral tablet, syrup	Look	10 mg 25 mg, 50 mg, 100 mg; 10 mg/5 ml	25 to 100 mg orally once to four times daily depending upon indication
<b>Cetirizine (oral tablet/syrup)</b>	Look	5 mg, 10 mg; 1 mg/mL	5 to 10 mg orally once daily depending upon the severity of symptoms
<b>Certrid***</b> (rosuvastatin calcium and fenofibric acid)	Look	5 mg/135 mg, 10 mg/135 mg, 20 mg/135 mg, 5 mg/45 mg, 10 mg/45 mg	Single dose orally at any time of day
<b>Actonel</b> (risedronate sodium)	Look	5 mg, 30 mg, 35 mg, 75 mg, 150 mg	5 mg orally daily or 35 mg orally every week or 150 mg orally every month depending upon diagnosis
<b>Citrucel</b> (methylcellulose)	Look and Sound	500 mg tablet, 2 g powder per heaping tablespoon	2 tablets orally up to 12 tablets a day; One heaping tablespoonful in 8 oz cold water 1 to 3 times a day
<b>Cetacort</b> (hydrocortisone topical lotion)	Look	0.25%, 0.5%, 1%	Apply to affected area(s) two to four times daily

**Appendix H: Drug names that were past proposed proprietary names.**

<b>Proprietary Name</b>	<b>Similarity to Cetrazal</b>	<b>Status</b>

b(4)

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

**Appendix J:** Drug products with single strength but with multiple differentiating product characteristics.

<b>Product Name with potential for confusion</b>	<b>Similarity to Proposed Proprietary Name</b>	<b>Strength</b>	<b>Usual Dose:</b>	<b>Differentiating Product Characteristics</b>
<b>Cetrazal (ciprofloxacin otic solution)</b>	<b>N/A</b>	<b>0.2%</b>	<b>Contents of one unit-dose vial (0.25 mL) instilled into the affected ear (s) twice daily for 7 days</b>	
<b>Atralin (tretinoin topical gel)</b>	<b>Look</b>	<b>0.05%</b>	<b>Apply once a day before bedtime or in the evening.</b>	<b>Orthographic differences in suffixes exist between Atralin vs. Cetrazal ('-lin' vs. '-zal')</b> <b>Routes of administration is topical</b> <b>Frequency of administration is once daily</b>
<b>Letrozole (synonymous with letrozol per Micromedex)</b>	<b>Look</b>	<b>2.5 mg</b>	<b>One tablet once daily</b>	<b>Dosage form is tablet</b> <b>Route of administration is oral</b> <b>Frequency of administration is once daily</b>
<b>Letrozol (synonymous with letrozole per Micromedex)</b>	<b>Look</b>	<b>2.5 mg</b>	<b>One tablet once daily</b>	<b>Dosage form is tablet</b> <b>Route of administration is oral</b> <b>Frequency of administration is once daily</b>
<b>Anturo<sup>***</sup> (oxybutynin) gel</b>	<b>Look</b>	<b>3%</b>	<b>Apply 3 mL once daily to abdomen, inner and upper part of thighs, or upper arms/shoulders</b>	<b>Route of administration is topical</b> <b>Frequency of administration is once daily</b>
<b>Citanest</b>	<b>Look</b>	<b>4%</b>	<b>Administer 8 mg/kg</b>	<b>Route of administration</b>

(prilocaine) Injection			(patients who weigh < 150 lbs) to 600 mg (patients who weigh ≥ 150 lbs) subcutaneously for local anesthesia during dental procedures	is subcutaneous Frequency of administration is once (and as necessary) Additionally, the practice setting for the use of Citanest is in a dentist's office to be used prior to a procedure
Acthrel (corticotropin ovine trifluate) injection	Look	100 mcg	Single intravenous dose of 1 mcg/kg for testing pituitary corticotrophin function	Route of administration is intravenous Frequency of administration is one time Context of use is diagnostic aid
Colazal (balsalazide disodium)	Look	750 mg	Three capsules orally three times a day	Dosage form is capsule Route of administration is oral Frequency of administration is three times daily
CitraCal (calcium supplement)	Look and Sound	200 mg elemental calcium	800 mg to 1200 mg /day in divided doses (2 to 3 times per day) depending upon age	Dosage form is tablet Route of administration is oral

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

**Appendix J:** Biologic product prescribed in a non-traditional manner.

Product Name with potential for confusion	Similarity to Proposed Proprietary Name	Usual Dose:	Differentiating Product Characteristics
Cetraxal (ciprofloxacin otic solution)		Contents of one unit-dose vial (0.25 mL) instilled into the affected ear (s) twice daily for 7 days	
Carticel (autologous cultured chondrocytes) for implantation	Look	0.64 million to 3.3 million cells/cm <sup>2</sup>	Route of administration is intracellular/implantation Frequency of administration is one time after procedure Practice setting is surgical

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/s/

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**CONSULTATION RESPONSE**

**DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT  
OFFICE OF DRUG SAFETY  
(DMETS; White Oak 22, Mail Stop 4447)**

**DATE RECEIVED:**

June 6, 2005

**DOCUMENT DATE:**

May 4, 2005

**DESIRED COMPLETION DATE:**

September 1, 2005

**PDUFA DATE:** April 9, 2006

**ODS CONSULT #:** 05-0132

**TO:**

Janice Soreth, M.D.  
Director, Division of Anti-Infective and Ophthalmology Products  
HFD-520

**FROM:**

Todd D. Bridges, R.Ph., Safety Evaluator  
Division of Medication Errors and Technical Support

**THROUGH:**

Nora Roselle, Pharm.D., Acting Team Leader  
Denise Toyer, Pharm.D., Deputy Director  
Carol Holquist, R.Ph., Director  
Division of Medication Errors and Technical Support

**PRODUCT NAME:**

Cetraxal<sup>®</sup>  
(Ciprofloxacin Otic Solution) 0.2%

**SPONSOR:** Salvat, S.A.

**NDA#:** 21-918 (IND#: 67,173)

**RECOMMENDATIONS:**

1. DMETS has no objections to the use of the proprietary name, Cetraxal<sup>®</sup>. However, DMETS does not recommend use of the proposed low density polyethylene (LDPE) vials for otic solutions for the reasons described in Section II of this review. This name evaluation is considered a tentative decision and the firm should be notified that this name with its associated labels and labeling must be re-evaluated approximately 90 days prior to the expected approval of the NDA. A re-review of the name prior to NDA approval will rule out any objections based upon approvals of other proprietary or established names from the signature date of this document.
2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review in order to minimize potential errors with the use of this product.
3. DDMAC finds the proprietary name, Cetraxal<sup>®</sup>, acceptable from a promotional perspective.

Division of Medication Errors and Technical Support  
Office of Drug Safety  
WO 22, MAIL STOP 4447  
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: July 7, 2005  
NDA#: 21-918 (IND#: 67,173)  
NAME OF DRUG: Cetraxal®  
(Ciprofloxacin Otic Solution) 0.2%  
NDA SPONSOR: Salvat, S.A.

I INTRODUCTION

This consult was written in response to a request from the Division of Anti-Infective and Ophthalmology Drug Products (HPD-520), for an assessment of the proprietary name, Cetraxal®, regarding potential name confusion with other proprietary or established drug names. Container labels, carton and insert labeling were submitted for review and comment.

PRODUCT INFORMATION

Cetraxal® (Ciprofloxacin Otic Solution) is a broad-spectrum fluoroquinolone antibacterial agent for otic use. Cetraxal® is indicated for the treatment of acute diffuse otitis externa in adult and pediatric patients, one year and older, due to susceptible strains of *Pseudomonas aeruginosa* and *Staphylococcus aureus*. The dose is the contents of one unit-dose vial (0.25 mL) instilled into the affected ear(s) twice daily for seven days. Cetraxal® is supplied as fourteen plastic, unit-dose vials in a foil pouch. Each foil pouch contains twist top vials and each vial contains 0.25 mL of Ciprofloxacin Otic Solution. The vials are not loose in the foil pouch but are attached to one another and form a strip (see Figure 1 below).

b(4)



Figure 1. Partial strip of Cetraxal® vials.

## II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of several standard published drug product reference texts<sup>i</sup> as well as several FDA databases<sup>ii</sup> for existing drug names which sound-alike or look-alike to Cetraxal® to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database<sup>iv</sup> and the data provided by Thomson & Thomson's SAEGIS™ Online Service<sup>v</sup> were also conducted. An Expert Panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name.

### A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Cetraxal. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC has no objections to the proposed proprietary name, Cetraxal, from a promotional perspective.
2. The Expert Panel identified three proprietary names which were thought to have the potential for confusion with Cetraxal. These products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

<sup>i</sup> MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

<sup>ii</sup> Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

<sup>iii</sup> AMP Decision Support System [DSS], the Division of Medication Errors and Technical Support proprietary name consultation requests, New Drug Approvals 1998-2004, and the electronic online version of the FDA Orange Book.

<sup>iv</sup> WWW location <http://www.uspto.gov>.

<sup>v</sup> Data provided by Thomson & Thomson's SAEGIS(tm) Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com).

Table 1: Potential Sound-Alike/Look-Alike Names Identified for Cetraxal

Product Name	Dosage/form(s), Established name	Usual adult dose	Other
Cetraxal	Ciprofloxacin 0.2% eye solution	Instill the contents of one single dispensing unit (0.25 mL) into affected ear(s) twice daily for seven days.	N/A
Citracal	Calcium citrate 200 mg tablets; Calcium citrate and vitamin D caplets 315 mg/200 IU; Calcium citrate and vitamin D tablets 250 mg/62.5 IU; Calcium citrate, vitamin D, magnesium (and other nutrients) tablets 250 mg/125 IU/80 mg	1 to 2 tablets or caplets twice a day.	LA/SA
Citrucel	Methylcellulose 2 gram/scoop (tablespoonful) powder;  500 mg tablets	Dissolve one scoop in water and drink up to three times daily.  2 to 4 tablets as needed up to 12 per day.	LA/SA
Trexall	Methotrexate sodium Tablets: 5 mg, 7.5 mg, 10 mg, 15 mg	<u>Choriocarcinoma and similar trophoblastic diseases:</u> 15 mg to 30 mg daily for a five-day course. <u>Acute lymphoblastic leukemias:</u> Induction of remission: 3.3 mg/m <sup>2</sup> in combination with 60 mg/m <sup>2</sup> of prednisone given daily. Maintenance therapy: 2 times weekly in total weekly doses of 30 mg/m <sup>2</sup> . <u>Lymphomas:</u> in Burkitt's tumor, Stages I-II: 10 mg to 25 mg/day orally for 4 to 8 days. Stage III: combined drug therapy with MTX given in doses of 0.625 mg to 2.5 mg/kg daily. <u>Mycosis fungoides (cutaneous T cell lymphoma):</u> 5 mg to 50 mg once weekly. Twice weekly in doses ranging from 15 mg to 37.5 mg in patients who have responded poorly to weekly therapy. <u>Psoriasis and rheumatoid arthritis:</u> 7.5 mg to 30 mg once a week or 3 consecutive doses at 12 hour intervals up to 30 mg/week - given as a course once weekly.	SA
*Frequently used, not all-inclusive. **LA (look-alike), SA (sound-alike)			

B. PHONETIC 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. The phonetic search modules return a numeric score to the search engine based on the phonetic similarity to the input text. Likewise, an orthographic algorithm exists which operates in a similar fashion. All names identified by POCA as having significant phonetic or orthographic similarities to Cetraxal were discussed by the Expert Panel (EPD).

**C. PRESCRIPTION ANALYSIS STUDIES**

**1. Methodology:**

Three separate studies were conducted within FDA for the proposed proprietary name to determine the degree of confusion of Cetraxal with other U.S. drug names due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. Each study employed a total of 123 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Cetraxal (see below). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were 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 sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
<p><u>Outpatient RX:</u></p> <p><i>Cetraxal 0.2% solution</i>  <i>#1 instill 1 drop into affected</i>  <i>eye) bid for 7 days</i></p>	<p>Cetraxal 0.2% Solution            Dispense 1            Instill 1 drop to the affected ear            twice daily for 7 days</p>
<p><u>Inpatient RX:</u></p> <p><u><i>Cetraxal 0.2% Solution</i></u>  <u><i>instill 1 drop qd bid x 7 days</i></u></p>	

**2. Results:**

One respondent in the outpatient prescription study interpreted the proposed proprietary name as Ataraxal and nine additional respondents from the same study interpreted the name as Atraxal. Ataraxal and Atraxal can potentially look similar to the currently marketed U.S. product Atarax. See Appendix A (page 14) for the complete listing of interpretations from the verbal and written studies.