CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-777

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)

DATE RECEIVED: July 28, 2004 **DATE OF DOCUMENT:** April 30, 2004	**DESIRED COMPLETION DATE:** September 27, 2004 **PDUFA DATE:** February 28, 2005	**ODS CONSULT #:** 04-0196

TO: Brian Harvey, MD
Acting Director, Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products
HFD-550

THROUGH: Paul Balcer
Project Manager
HFD-550

PRODUCT NAME: **Amrix** (Cyclobenzaprine HCL Modified Release Capsules) 15 mg and 30 mg NDA#: 21-777	**NDA SPONSOR:** ECR Pharmaceuticals

SAFETY EVALUATOR: Kimberly Culley, RPh

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary name, Amrix. This 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 Amrix acceptable from a promotional perspective.

4. DMETS recommends consulting Guiragos Poochikian of the Labeling and Nomenclature committee for proper designation of the established name.

Carol Holquist, RPh
Director
Division of Medication Errors and Technical Support
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Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: September 13, 2004

NDA# 21-777

NAME OF DRUG: **Amrix** (Cyclobenzaprine HCL Modified Release Capsules)
15 mg and 30 mg

NDA HOLDER: ECR Pharmaceuticals

I. INTRODUCTION:

This consult was written in response to a request from the Division of Anti-Inflammatory, Analgesic and Ophthalmologic Drug Products (HFD-550) for an assessment of the proprietary name, Amrix, in regard to potential name confusion with other proprietary or established drug names. Container labels and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Amrix contains cyclobenzaprine hydrochloride in a modified-release oral formulation for the treatment of muscle spasm associated with acute, painful musculoskeletal conditions. This is to be used as an adjunct to rest and physical therapy. Due to a lack of evidence of effectiveness for more prolonged use, cyclobenzaprine should only be used up to two or three weeks. Amrix will be dosed at 15 mg once daily up to 30 mg daily. The sponsor suggests the capsules to be taken at the approximate same time each day. If the patient is hepatically impaired or elderly, the recommended dose is 15 mg daily. Amrix will be available in bottles of 60 tablets for both the 15 mg and 30 mg strengths. The 15 mg capsules will be orange on orange and embossed with ECR 15 on each half with a single white band. The 30 mg capsules will be blue and orange with embossed ECR 30 on each half with two white bands. Physician samples will be packaged in individual blisters with each sample comprised of one capsule.

II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts[1,2] as well as several FDA databases[3] for existing drug names which sound-alike or look-alike to Amrix 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 was also conducted[4]. 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 (EPD)

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

1. DDMAC finds the proprietary name Amrix acceptable from a promotional perspective.

2. The Expert Panel identified ten proprietary names that were thought to have the potential for confusion with Amrix. Additionally, two names were identified by prescription studies, Aricept and Amaryl. These products with their available dosage forms and usual dosage are listed in table 1 (see page 4, 5 and 6).

[1] MICROMEDEX Integrated Index, 2004, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-04, and the electronic online version of the FDA Orange Book.
[4] WWW location http://tess2.uspto.gov/bin/gate.exe?f=searchstr&state=m2pu5u.1.1

Table 1:	Potential Sound-Alike/Look-Alike Names Identified by DMETS for the proposed name of Amrix		
PRODUCT NAME	**ESTABLISHED NAME AND AVAILABLE STRENGTHS**	**USUAL ADULT DOSE***	**OTHER****
Amrix®	Cyclobenzaprine HCL Modified-release Capsules, 15 mg and 30 mg	One 15 mg capsule once daily. Some patients may require up to 30 mg per day. Should be used for less than two to three weeks.	
Alrex®	Loteprednol Etabonate Ophthalmic suspension, 0.2%	Instill 1 drop into the affected eye(s) 4 times daily	LA/SA
Amaryl®	Glimenepiride Tablets 1 mg, 2 mg, and 4 mg	Initial dosing: 1 to 2 mg once daily, given with breakfast or the first main meal of the day. Maintenance dosing: 1 to 4 mg once daily, with a maximum of 8 mg once daily.	
Amcort®	Triamcinolone Diacetate Injection 40 mg/mL	Intramuscular for initial therapy: Average dose is 40 mg IM per week. In general, a single parenteral dose 4 to 7 times the oral daily dose controls the patient from 4 to 7 days, up to 3 to 4 weeks. Intra-articular and intrasynovial: 5 to 40 mg. Intralesional or sublesional: 5 to 48 mg. Do not use more than 12.5 mg per injection site. The usual average dose is 25 mg per lesion.	LA
Amicar®	Aminocaproic Acid Injectable: 250 mg/mL Syrup: 250 mg/mL (1.25 Grams/5 mL) Tablets: 500 mg	Initial dose of 5 g orally or IV, followed by 1 g hourly, should achieve and sustain drug plasma levels at 0.13 mg/mL. This is the concentration apparently necessary for inhibition of fibrinolysis. Administration of more than 30 g/24 hours is not recommended. Intravenous for treatment of acute bleeding syndromes: 4 to 5 g in 250 mL of diluent by infusion during the first hour, followed by continuous infusion at the rate of 1 g/hour in 50 mL of diluent. Continue for 8 hours or until bleeding is controlled. Oral for the treatment of acute bleeding syndromes: 5 g orally during the first hour of treatment, followed by a continuing rate of 1 g/hour. Continue this method of treatment for about 8 hours or until bleeding has been controlled	LA

Table 1:	Potential Sound-Alike/Look-Alike Names Identified by DMETS for the proposed name of Amrix		
PRODUCT NAME	**ESTABLISHED NAME AND AVAILABLE STRENGTHS**	**USUAL ADULT DOSE***	**OTHER****
Amrix®	Cyclobenzaprine HCL Modified-release Capsules, 15 mg and 30 mg	One 15 mg capsule once daily. Some patients may require up to 30 mg per day. Should be used for less than two to three weeks.	
Amvaz ™ (discontinued from US market)	Amlodipine Tablets: 2.5 mg, 5 mg and 10 mg	Hypertension: Dosage is individualized, with usual dose of 5 mg once daily, maximum dose of 10 mg once daily. Angina: 5 to 10 mg	LA
Amvisc®	Sodium Hyaluronate Injection, 12 mg/mL	Cataract surgery/Intracocular lens implantation: Slowly introduce a sufficient amount (using cannula or needle) into anterior chamber. Inject either before or after delivery of lens. Glaucoma filtration surgery: In conjunction with the performance of the trabeculectomy, inject slowly and carefully through a corneal paracentesis to reconstitute the anterior chamber. Further injection can be continued to allow it to extrude into the subconjunctival filtration site through and around the sutured outer scleral flap. Corneal transplant surgery: After removal of the corneal button, fill the anterior chamber with the drug. Then, suture the donor graft in place. An additional amount may be injected to replace the lost amount as a result of surgical manipulation. Sodium hyaluronate has also been used in the anterior chamber of the donor eye prior to trepanation to protect the corneal endothelial cells of the graft. Retinal attachment surgery: Slowly introduce into the vitreous cavity. The injection may be directed to separate membranes from retina for safe excision and release of traction. Also serves to maneuver tissues into desired position (e.g., to gently push back a detached retina or unroll a retinal flap); aids in holding retina against the sclera for reattachment.	LA/SA
Aricept®	Donepezil Tablets, 5 mg and 10 mg	5 to 10 mg once daily	LA
Arimidex®	Anastrozole Tablets, 1 mg	1 mg once daily. For adjuvant treatment of early breast cancer in postmenopausal women, the optimal duration of therapy is unknown. The median duration of therapy at the time of data analysis was 31 months; the ongoing ATAC trial is planned for 5 years of treatment.	LA/SA

Table 1:	Potential Sound-Alike/Look-Alike Names Identified by DMETS for the proposed name of Amrix		
PRODUCT NAME	**ESTABLISHED NAME AND AVAILABLE STRENGTHS**	**USUAL ADULT DOSE***	**OTHER****
Amrix®	Cyclobenzaprine HCL Modified-release Capsules, 15 mg and 30 mg	One 15 mg capsule once daily. Some patients may require up to 30 mg per day. Should be used for less than two to three weeks.	
Atarax®	Hydroxyzine HCL Injection: 25 mg/mL, 50 mg/mL (1mL, 2mL and 10 mL vials) **Syrup: 10 mg/5 mL (only marketed Atarax brand product)** Tablet: 10 mg, 25 mg, 50 mg	Parenteral (deep intramuscular administration only (preferred site is the upper outer quadrant of the buttock or the midlateral thigh) Anxiety: 50 to 100 mg 4 times a day. Pruritus: 25 mg 3 or 4 times a day. Sedative/premedication and following general anesthesia): 50 to 100 mg and children, 0.6 mg/kg. Antiemetic/Analgesia, adjunctive therapy (parenteral only): 25 to 100 mg IM for adults. 1.1 mg/kg (0.5 mg/lb) IM for children For Oral Use: Anxiety: 50 to 100 mg 4 times a day, for adults. 50 to 100 mg/day in divided doses, for children greater than 6 years and 50 mg/day in divided doses for children less than 6 years. Pruritus: 25 mg 3 or 4 times daily for adults, 50 to 100 mg/day in divided doses for children greater than 6 years and 50 mg/day in divided doses for children less than 6 years. Sedative/premedication and following general anesthesia: 50 to 100 mg for adults and 0.6 mg/kg for children	LA
Cormax™	Clobetasol Proprionate Topical Cream, 0.05% (cream, ointment and scalp application)	Apply sparingly to affected areas 2 to 4 times daily.	LA/SA
Eprex® (Canadian drug)	Erthropoetin Injection: 2000 Units/mL, 4000 Units/mL, 10,000 Units/mL, 20,000 Units/mL		SA
Eurax®	Crotamiton Cream and Lotion, 10%	For scabies, thoroughly massage into the skin of the whole body from the chin down, paying particular attention to all folds and creases. A second application is advisable 24 hours later. Change clothing and bed linen the next morning. Take a cleansing bath 48 hours after the last application. For pruritus, massage gently into affected areas until medication is completely absorbed. Repeat as necessary.	LA
*Frequently used, not all-inclusive. **L/A (look-alike), S/A (sound-alike)			

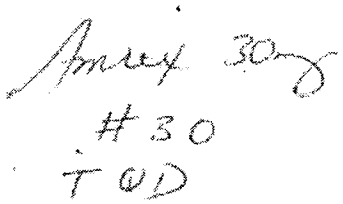
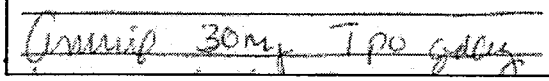
B. PHONETIC and ORTHOGRAPHIC COMPUTER ANALYSIS (POCA)

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. The phonetic search module returns 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 considered to have significant phonetic or orthographic similarities to Amrix were captured by the Expert Panel (EPD).

C. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Amrix 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. These studies 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 Amrix (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 and sent to a random sample of the participating health professionals for their interpretation 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
Outpatient RX: 	Amrix 30 mg One po daily Number 30
Inpatient RX: 	

2. Results:

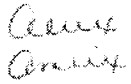
One respondent of the outpatient study interpreted the proposed name as Aricept®. Aricept is a currently marketed U.S. product. Another respondent of the inpatient study interpreted the proposed name as Amuril®. Amuril is an animal-use product not currently marketed in the United States. See appendix A for the complete listing of interpretations from the verbal and written studies.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Amrix, the primary concerns related to look-alike and sound-alike confusion with Alrex, Amaryl, Amcort, Amicar, Amvaz, Amvisc, Arimidex, Atarax, Cormax, Eprex, and Eurax. Upon further review of the names gathered from EPD and independent analysis, the names Amcort, Amicar, Amvaz, Arimidex, and Cormax were not reviewed further due to a lack of convincing look-alike or sound-alike similarities with Amrix. Furthermore, Amcort, Amicar, and Cormax differ in strength, dosing frequency, dosage form, and indication of use. Amvaz and Arimidex share the characteristics of oral and daily use. However, Amvaz is no longer marketed in the US and differs in strength, dosing and indication of use. Arimidex also differs in strength, dosing and indication of use.

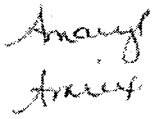
Additionally, DMETS conducted prescription studies to simulate the prescription ordering process. The studies identified an additional name of concern, Aricept. One respondent in the outpatient study interpreted the proposed name as Aricept®. Aricept is a currently marketed U.S. product. In addition, one respondent in the inpatient study interpreted the proposed name as Amuril®. Amuril is an animal-use product not currently marketed in the United States and will not be reviewed further. In addition, one voice participant interpreted the name with the spelling of "Amryx." DMETS will review the name of Amaryl due to the combination of the Amuril (visual) interpretation and the Amryx (verbal).

1. Alrex may look and sound similar to Amrix when scripted and spoken. Alrex contains loteprednol in a 0.2 % ophthalmic suspension, which is used in temporary relief of signs and symptoms of seasonal allergic conjunctivitis and for inflammatory conditions such as allergic conjunctivitis, acne rosacea, superficial punctate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitis, and inflammation following ocular surgery. Alrex is available in 5 and 10 mL bottles. The primary auditory and visual similarities involve the shared leading "a", central "r" and concluding "x" (see below). In addition, when scripted, the "e" of Alrex may resemble the "i" of Amrix. However, the "l" of Alrex and "m" Amrix should provide a decisive characteristic in speech.



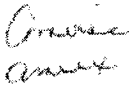
Furthermore, the products do not share overlapping characteristics, such as dosage form (suspension compared with capsules), route of administration (ophthalmic compared with oral), strength (0.2% compared with 15 mg and 30 mg), indication of use (ocular inflammation due to allergic conjunctivitis compared with muscle spasm), and dosing frequency (four times daily compared with daily). Due to the aforementioned differences between Alrex and Amrix, DMETS believes the chance of error is minimal.

2. Amaryl may look similar to Amrix when scripted. Amaryl contains glimepiride tablets in strengths of 1 mg, 2 mg, and 4 mg and is indicated for the treatment of hyperglycemia in non-insulin dependent diabetes. Amaryl may be used in conjunction with metformin, oral hypoglycemia agents and insulin. Initial dosing is recommended at 1 to 2 mg daily with maintenance therapy of 1 to 4 mg once daily. The primary visual similarities involve the shared leading "Am" and central "r" (see below). In addition, the "l" of Amaryl may resemble the "x" of Amrix. However, the "y" of Amaryl should serve as a distinguishing mark.



The products share the frequency of dosing (daily) and route of administration (oral), but differ in strength (1 mg, 2 mg, 4 mg compared with 15 mg and 30 mg), indication (hyperglycemia compared with muscle relaxation) and duration of therapy (indefinite compared with less than three weeks of therapy). Although practitioners may misspell the Amrix as Amryx when the product is first introduced to the marketplace (therefore creating a strong visual similarity), the lack of overlapping characteristics should serve to prevent an error from occurring until the product name becomes more familiar. As the orthographic similarities are weak and the products do not share significant overlapping characteristics, DMETS believes the possibility of error to be minimal.

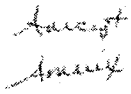
3. Amvisc may look and sound similar to Amrix when scripted and spoken. Amvisc contains sodium hyaluronate as an injection (12 mg/mL) for use as a surgical aid to maintain a deep anterior chamber, push back the vitreous face, prevent formation of a postoperative flat chamber, and create a clear field of vision by facilitating intra- and post-operative inspection of the retina and photocoagulation. This product is available as 0.5 or 0.8 mL disposable syringes, which are stored under refrigeration. The primary auditory similarities involve the shared leading "am" and the comparable sound of "sc" and "x" when spoken. The primary visual similarities involve the shared leading "am" and likeness of "v" and "r" when scripted (see below).



Although the verbal and visual similarities are significant, the products share no overlapping characteristics. They differ in route of administration (intraocular compared with oral), strength (12 mg/mL compared with 15 mg and 30 mg), indication (surgical aid compared with muscle relaxant), context of use (operating room compared with inpatient/outpatient use), method of storage (refrigerated compared with room temperature), and dosage form (solution in disposable syringes compared with capsules). Therefore, DMETS believes the possibility of error to be minimal.

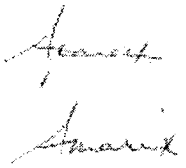
4. Aricept may look similar to Amrix when scripted. This was confirmed by one respondent of the outpatient study who interpreted the proposed name as Aricept. Aricept contains donepezil in 5 mg and 10 mg tablet for the treatment of mild to moderate dementia associated with Alzheimer's disease. Aricept is dosed at 5 to 10 mg once daily and is available in bottles of 30 tablets and unit dose packages of 100 tablets. The primary visual similarities involve the shared leading "a", which is compounded by the likeness of "ri" and "m", central "c" and "r"

and the concluding "t" and "x" when scripted (see below). However, the "p" of Aricept with its downstroke may provide a distinctive characteristic to differentiate the names.



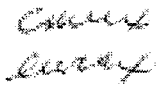
The products share the frequency of dosing and route of administration. They differ in strength (5 mg and 10 mg compared with 15 mg and 30 mg), indication (dementia associated with Alzheimer's disease compared with muscle relaxation) and duration of therapy (indefinite compared with less than three weeks). However, prescriptions for Aricept should be written for a number 30 or greater and Amrix, less than 30, which should aid in differentiation. DMETS acknowledges that the possibility of the 5 mg and 10 mg may be confused with 15 mg due to a resemblance when scripted; but the probability of misinterpretation of all the contributing factors should be low. Due to the low orthographic similarities and differences in product characteristics, DMETS anticipates minimal chance of confusion.

5. Atarax may look similar to Amrix when scripted. Atarax contains hydroxyzine hydrochloride for the treatment of anxiety, pruritus from allergic conditions such as chronic urticaria, atopic and contact dermatoses. It can also be used as a premedication sedative or following general anesthesia (oral only), as an antiemetic (parenteral only) to control nausea and vomiting and as an analgesic (parenteral only) to permit reduction in narcotic dosage. The Atarax brand is only marketed as a syrup; however, this is a brand name that is significantly associated with the generic product. Practitioners often write prescriptions for the brand Atarax in both the tablet and injectable formulation, therefore DMETS will review all strengths and formulations to be inclusive. The primary visual similarities involve the shared leading "a", central "ar" and concluding "x" (see below). This is could be compounded by the resemblance of "a" and "i" in hurried scripting. However, the leading "t" with the upstroke is hard to diminish; therefore creating a significant marker for name recognition.



The products share an overlapping route of administration (oral) and two possible dosing overlaps in pediatric dosing of Atarax. The first involves the intramuscular, antiemetic indication of Atarax in children (1.1 mg/kg) and the second is the oral pediatric sedative indication (0.6 mg/kg). However, prescriptions will typically be written to correspond to their actual route of administration (e.g. one teaspoonful, 5 mL) that should help to distinguish the two drug products. Since oral Atarax syrup is only available in one strength, practitioners will tend not to indicate strength, but will note dose (by measurement, teaspoonful or milliliter) and dispensing amount (ounces or milliliters) that will serve to differentiate the products and negate the overlapping strength. Overall, the two medications do not share any additional overlapping characteristics, such strength (50 mg/mL, 250 mg/mL, 10 mg/5 mL, 10 mg, 25 mg and 50 mg compared with 15 mg and 30 mg), indication (primarily pruritus compared muscle relaxation), and standard dosing frequency (three to four times daily compared with daily). DMETS believes the possibility of confusion between these two names to be limited.

6. Eurax may look similar to Amrix when scripted. Eurax contains crotamiton as a 10% cream, ointment, and scalp application (lotion) for the treatment of scabies or pruritic skin. The drug product is thoroughly massaged into the skin of the entire body from the chin down with a second application 24 hours later for scabies, with the treatment for pruritus to be massaged gently into affected areas until medication is completely absorbed. The drug product may be re-administered if necessary. The primary visual similarities involve the shared central "r" and concluding "x" with the possibility of the leading "e" and "a" to have a resemblance when scripted in lower case (see below).



However, the drug products do not share any overlapping characteristics, such as route of administration (topical compared with oral), strength (10% compared 15 mg and 30 mg), dosage form (cream/lotion/ointment compared with capsules), and indication (scabies/pruritus compared with muscle spasm). These differences will minimize the potential for error.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels, cartons and insert labeling of Amrix, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. GENERAL COMMENTS

We note the established name reflects "modified release" as it is the dosage form. The term modified-release is not a dosage formulation recognized by the US Pharmacopeia (USP). We recommend consulting the CDER Labeling and Nomenclature committee on the proper designation of the established name. For example,

Amrix®
Cyclobenzaprine Hydrochloride Extended-release Capsules

B. CONTAINER LABEL (60's and Physician Samples)

Please adjust the presentation of the proprietary name, established name and strength to increase the relative prominence of theses important labeling statements. Also include the unit of measure in conjunction with the number. The current presentation is confusing due to the cumbersome arrangement and the fact that the "15" and "30" appear to be part of the proprietary name without reference to measurement of strength (milligram). Revise as follows:

Amrix
Cyclobenzaprine Hydrochloride Extended-Release Capsules
15 mg

If the reference to dosing schedule remains, please revise to read "Once daily dosing." This will help to simplify the label and create less distraction and clutter with the deletion of the addition

words ("And Provides for") that provide no pertinent information.

C. CARTON LABEL (Physician Sample and External Corrugated Carton)

See comment B.

IV. RECOMMENDATIONS:

A. DMETS has no objections to the use of the proprietary name, Amrix. This 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.

B. DMETS recommends implementation of the label and labeling revisions outlined in section III of this review to minimize potential errors with the use of this product.

C. DDMAC finds the proprietary name Amrix acceptable from a promotional perspective.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Sammie Beam, project manager, at 301-827-2102.

Kim Culley, RPh
Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Alina Mahmud, RPh
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

Appears This Way
On Original

Appendix A: DMETS Prescription Study Results (Amrix)

Inpatient	Outpatient	Voice
Amrix	Aricept	Amrix
Avirix	Amrex	Amrix
Amril	Amrex	Amrix
Amril	Amrex	Amrix
Amrix	Amrix	Amrix
Amuril	Amrix	Amrex
Amrix	Amrix	Amrix
Amril	Amrix	Amrex
Amvil	Amrex	Amrix
Ammril	Amrex	Amerix
Amrix	Amirex	Amerix
Amril	Amrix	Amrex
Anirix	Amrix	Amryx
Amril	Amrix	Amrix
Ammie	Amrex	Amrix
Amris	Amrex	Amurex
Amril	Amrix	Amrix
Amrix	Amrex	Amrix
	Amrix	
	Amrix	
	Amrix	
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Kimberly Culley
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DRUG SAFETY OFFICE REVIEWER

Alina Mahmud
12/10/04 01:44:30 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
12/10/04 03:23:29 PM
DRUG SAFETY OFFICE REVIEWER