CENTER FOR DRUG EVALUATION AND RESEARCH

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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:	February 26, 2009
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Subject:	Proprietary Name Review
Drug Name(s):	Colcrys (Colchicine) Tablets 0.6 mg
Application Type/Number:	NDA 22-351 NDA 22-352 NDA 22-353
Applicant/Applicant:	United Research Laboratories, Inc. Mutual Pharmaceutical Company, Inc.
OSE RCM #:	2008-2050

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EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name, Colcrys, is not vulnerable to name confusion that could lead to medication errors. Thus, DMEPA has no objection to the proprietary name Colcrys for this product. The Division of Anesthesia, Analgesia, and Rheumatology Products concurs with this assessment.

However, if any of the approved product characteristics as stated in this review are altered, 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 In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject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.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from the Division of Anesthesia, Analgesia, and Rheumatology Products for an assessment of the proposed proprietary name, Colcrys, regarding potential name confusion with other proprietary or established drug names in normal practice settings.

1.2 REGULATORY HISTORY

The Division of Medication Error and Analysis objected to the Applicant's original proposed proprietary name, Colstat, in OSE Review 2008-1643, dated December 5, 2008, because the proposed name contained a United States Adopted Name (USAN) stem.

In response, URL Mutual submitted a request for a proprietary name review dated December 19, 2008. The Applicant's first choice for the proprietary name for Colchicine Tablets USP is Colcrys (pronunciation 'kol-kris'). DMEPA's risk assessment of the proposed proprietary name, Colcrys, is the subject of this review.

1.3 PRODUCT INFORMATION

Colchicine tablets are currently marketed in the United States without an approved NDA. The applicant is seeking NDA approval for Colcrys (Colchicine) for the following indications: the treatment of gout flares, the prevention of gout flares, and the treatment of adults and children ≥ 4 years of age with Familial Mediterranean Fever (FMF). Colcrys tablets are immediate-release tablets for oral administration, and may be given without regard to meals. The recommended dosing regimen varies depending on the indication of use.

For treatment of a gout flare, the recommended dose of Colcrys is 1.2 mg (2 tablets) at the first sign of a flare followed by 0.6 mg (1 tablet) one hour later. The maximum recommended dose for the treatment of gout flares is 1.8 mg over a 1 hour period. ——————————————— b(4)

For the prevention of gout flares in adults and adolescents older than 16 years of age, the recommended dosage of Colcrys is 0.6 mg once or twice daily. The maximum recommended dose for the prevention of gout flares is 1.2 mg per day.

For Familial Mediterranean Fever (FMF) the recommended dosages are as follows:

Age	Daily Dose	
	Usual	Maximum
Adults and children > 12 years	[redacted]	2.4 mg
Children > 6 to 12 years	[redacted]	
Children 4 to 6 years	0.3 mg [redacted]	

b(4)

Colcrys 0.6 mg tablets are scored, purple, film-coated and capsule-shaped. Colcrys will be available in bottles of 30, 60, 100, 250, 500 and 1000 tablets, and in [redacted]. Colcrys tablets should be stored at controlled room temperature (20° C to 25° C) and protected from light.

b(4)

2 METHODS AND MATERIALS

This section describes the methods and materials used by DMEPA staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment). The primary focus for the assessment is to identify and remedy potential sources of medication error prior to drug approval. 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. [1]

2.1 PROPRIETARY NAME RISK ASSESSMENT

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name, Colcrys, 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 CDER and CBER.

For the proprietary name, Colcrys, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). DMEPA normally conducts internal FDA prescription analysis studies and, when provided, external prescription analysis studies results are considered and incorporated 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 (see detail 2.1.2). The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [2] FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

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[1] National Coordinating Council for Medication Error Reporting and Prevention. http://www.nccmerp.org/aboutMedErrors.html. Last accessed 10/11/2007.

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

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. As such, the staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since 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 drug name include, but are not limited to established name of the proposed product, the proposed indication, 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 considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[3]

2.1.1 Search Criteria

The DMEPA staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter 'C' 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.[4,5]

To identify drug names that may look similar to Colcrys, the staff also considers the other orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the number of words in the name (one), the length of the name (seven letters), upstrokes (two, capital letter 'C' and lower case 'l'), downstrokes (one, lower case 'y'), cross-strokes (none), and dotted letters (none). Several letters in Colcrys may be vulnerable to ambiguity when scripted, including the letter 'C' may appear as 'A,' or 'G'; lower case 'o' may appear as a lower case 'a', 'e', 'i', or 'u'; lower case 'l' may appear as lower case 'e'; lower case 'c' may appear as 'e' or 'i'; lower case 'cr' may appear as a lower case 'u'; lower case 'y' may appear as a lower case 'z'; and lower case 's' may appear as a lower case 'r'. As such, the staff also considers these alternate appearances when identifying drug names that may look similar to Colcrys.

When searching to identify potential names that may sound similar to Colcrys, the DMEPA staff searches for names with similar number of syllables (two), stresses (COL-crys and col-CRYS), and placement of vowel and consonant sounds. As such, the staff also considers these alternate pronunciations when identifying drug names that may sound similar to Colcrys. The Applicant's intended pronunciation of the proprietary name (kol-kris) was provided with the request for a proprietary name review submission, and is also taken into consideration.

The staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately

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

[4] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[5] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artifical Intelligence in Medicine (2005)

determine the use of the product in the clinical practice setting For this review, DMEPA staff were provided with the following information about the proposed product: the proposed proprietary name (Colcrys), the established name (Colchicine), proposed indication [(treatment of gout, prevention of gout flares, and the treatment of adults and children ≥ 4 years of age with Familial Mediterranean Fever (FMF)], strength (0.6 mg), dose (0.3 mg, 0.6 mg, 0.9 mg, or 1.2 mg), frequency of administration (once for treatment of an acute attack, or once of twice daily for prevention of gout flares and the treatment of FMF), route of administration (oral), and dosage form of the product (tablet). Appendix A provides a more detailed listing of the product characteristics DMEPA staff generally take into consideration.

Lastly, the DMEPA staff also consider the potential for the proposed 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. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and DMEPA staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

2.1.1.1 Database and Information Sources

The proposed proprietary name, Colcrys, was provided to DMEPA staff to conduct a search 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 Colcrys using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the DMEPA staff uses 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, DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

2.1.1.2 FDA Expert Panel Discussion

An Expert Panel Discussion is held by DMEPA to gather CDER professional opinions on the safety of the product and the proprietary name, Colcrys. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of the Division of Medication Errors Prevention and Analysis staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

The pooled results of the DMEPA staff were presented 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 Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

2.1.2 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 Colcrys 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 a total of 122 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The results are used by the Safety Evaluator to identify any orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of Colcrys in handwriting and verbal communication of the name, inpatient medication orders 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 122 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 the medication error staff.

Figure 1. Colcrys Study (conducted on January 8, 2009)

HANDWRITTEN MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order 1: Colcrys 0.6mg 1 tablet by mouth bid	" Colcrys 0.6 mg, 1 tablet by mouth bid"
Inpatient Medication Order 2: Colcrys 0.6 mg #60 1 tab po bid	

2.1.3 Comments from the Division of Anesthesia, Analgesia, and Rheumatology Products

DMEPA requests the regulatory division in the Office of New Drugs responsible for the application for their comments and/or clinical/other concerns on the proposed proprietary name at 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. Any comments or concerns are addressed in the safety evaluator's assessment.

The Review Division is contacted a second time following our analysis of the proposed name. At this point, DMEPA conveys their decision to accept or reject the name. The regulatory division is requested to concur /not concur with DMEPA's final decision.

2.1.4 Safety Evaluator Risk Assessment of the Proposed Proprietary Name

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Mode and Effects Analysis and provide an overall risk 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 name to be confused with another drug name as a result of the name confusion and cause

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

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 look- or sound-alike drug names prior to approval, where actions to overcome these issues are easier and more effective then remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. 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 evaluation, and studies, and identifies potential failure modes by asking: "Is the name Colcrys 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 Colcrys 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 and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated to determine the likely *effect* of the drug name confusion, by asking "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 ultimately not be a source of medication errors in the usual practice setting, the name is eliminated 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 that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMEPA will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator's Risk Assessment:

1. 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 trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. 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)].
3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.

5. DMEPA staff identifies a potential source of medication error within the proposed proprietary name. 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.

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 is awarded approval first has the right to the use the name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

If none of these conditions are met, then DMEPA will not object to the use of the proprietary name. If any of these conditions are met, then DMEPA will object to the use of the proprietary 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 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, Joint Commission, and ISMP, who have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken 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 the approving the error-prone proprietary name. Moreover, even after Applicant's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, 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 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 FMEA process is used 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, and so DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error would render the proposed name acceptable.

3 RESULTS

3.1 PROPRIETARY NAME RISK ASSESSMENT

3.1.1 Database and Information Sources

The Division of Medication Error Prevention and Analysis' searches identified twenty-three names.

Sixteen of the twenty-three names were thought to look like Colcrys. They are: Calcijex, Colazal, Colyte, Colixin, ——— Colchica, ——— Caladryl, Ciltyri, Clolar, ——— Colocort, Colytrol, Colchicum, Cerebyx, and Cortosyn. b(4)

Four of the twenty-three names were thought to look and sound like Colcrys: Colcaps, Colrex, ——— (palamento liniment), and Clorpres.

The remaining three names were thought to sound like Colcrys: Coldmist JR, Coldmist LA, and Folcres.

Additionally, the Division of Medication Error Prevention and Analysis did not identify any United States Adopted Names (USAN) stems in the name, Colcrys, as of January 27, 2009.

3.1.2 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 or phonetic similarity to Colcrys. The Expert panel recommended that the primary safety evaluator conduct further searches to identify any names that begin with the letter 'G' that may look or sound like Colcrys. A search for look-alike 'G' names was conducted, however, no additional names were identified.

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 24 practitioners responded. Twenty-one of the participants interpreted the name correctly as "Colcrys," with correct interpretation occurring in the inpatient (n=6) and outpatient written studies (n=15). Two participants in the inpatient study misinterpreted the drug name as 'Colcryi'. The one response from the voice study overlapped with the existing drug name, Procrit. This additional name, which is thought to sound similar to Colcrys, was added to the list of 23 names previously identified as having some orthographic or phonetic similarity to Colcrys.

3.1.4 Comments from the Division of Anesthesia, Analgesia, and Rheumatology Products

In response to the OSE January 7, 2009, e-mail, DAARP did not forward any comments and/or clinical/other concerns on the proposed name at the initial phase of the name review.

DMEPA notified DAARP via e-mail that we had found no objections to the proposed proprietary name, Colcrys, on February 10, 2009. Per e-mail correspondence from the Division of Anesthesia, Analgesia, and Rheumatology Products on February 18, 2009, they indicated they concur with our assessment of the proposed name, Colcrys.

3.1.5 Safety Evaluator Risk Assessment

A total of twenty-four names were analyzed to determine if the drug names could be confused with Colcrys and if the drug name confusion would likely result in a medication error. Ten of the identified names were determined to have lack orthographic and/or phonetic similarity to Colcrys (see Appendix C).

The remaining 14 names were determined to have some orthographic and/or phonetic similarity to Colcrys, and thus determined to present some risk of confusion.

Failure mode and effect analysis was then applied to determine if the potential name, Colcrys, could potentially be confused with any of the 14 names and lead to medication errors. This analysis determined that the name similarity between Colcrys and the identified names was unlikely to result in medication errors with any of the 14 products identified for the reasons presented in Appendices D through I.

4 DISCUSSION

4.1 PROPRIETARY NAME RISK ASSESSMENT

Our evaluation identified 24 names having some similarity to the proposed name, Colcrys. However, FMEA findings indicate that the proposed name is not vulnerable to name confusion that could lead to medication errors for the reasons outlined in Appendices C through I.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Colcrys, is not vulnerable to name confusion that could lead to medication errors in the current marketplace. Thus we have no objections to the name, Colcrys, for this product. The Division of Anesthesia, Analgesia, and Rheumatology Products concurs with this assessment. However, if any of the approved product characteristics as stated in this review are altered; 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.

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 DMEPA on any communication to the Applicant with regard to this review. If you have further questions or need clarifications, please contact Chris Wheeler, project manager, at 301-796-0151.

5.2 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Colcrys, and have concluded that it is acceptable. The proposed proprietary name, Colcrys, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you. If **any** of the proposed product characteristics are altered prior to approval of the marketing application, the proprietary name should be resubmitted for review.

6 REFERENCES

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

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

2. ***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.

3. ***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.

4. ***AMF Decision Support System [DSS]***

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

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

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

Provides information regarding patent and trademarks.

9. ***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.

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)

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)

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.

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

List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

Contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

The DMEPA staff consider 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 proper 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 DMEPA staff also examine 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 DMEPA 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 (e.g.,"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 DMEPA compare 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	• 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-stokes 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

Appendix B: FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Medication Order	Voice Prescription
Colcrys	Colcrys	Procrit
Colcrys	Colcrys	
Colcrys	Colcrys	
Colcrys	Colcrys	
Colcrys	Colcrys	
Colcrys	Colcrys	
Colcryi	Colcrys	
Colcryi	Colcrys	
	Colcrys	
	Colcrys	
	Colcrys	
	Colcrys	
	Colcrys	
	Colcrys	
	Colcrys	

Appendix C: Names lacking convincing look-alike and/or sound-alike similarities with Colcrys

Proprietary Name	Similarity to Colcrys
———	Look
Caladryl	Look
Ciltyri	Look
Clolar	Look
———	Look
Colocort	Look
Colytrol	Look
Colchicum	Look
Cerebyx	Look
Cortosyn	Look

b(4)

Appendix D: Product names that have not ever been marketed.

Proprietary Name	Similarity to Colcrys	Status of product name
———	Look	DMEPA declined to review the proposed proprietary name ——— because the IND sponsor had not established a dose, thus the assignment was withdrawn from AIMS. ——— was to be supplied as a ——— injection for intravenous use for the treatment of ——— Thus far, no subsequent dosing information has been provided by the Applicant.
Colixin***	Look	Proposed proprietary name for colistimethate (ANDA 64-216). Name found unacceptable per OPDRA review dated 1/24/2000. This product is currently marketed under the established name per the FDA Orange Book and the labels/labeling in the last annual report.

b(4)

Appendix E: Products marketed in a foreign country

Proprietary Name	Similarity to Colcrys	Country
Colcaps Several formulations may be available: (phenylpropanolamine, phenylephrine, mepyramine, caffeine, salicylamide, chlorpheniramine) **or** (paracetamol, codeine, promethazine, pseudoephedrine) **or** (paracetamol, phenylephrine, vitamin C)	Look/Sound	South Africa
Folcres	Sound	Mexico: brand name for Minoxidil Argentina: brand name for Finasteride

Appendix F: Products withdrawn from the market.

Proprietary Name	Similarity to Colcrys
——— ——— Withdrawn in 1970	Look and Sound

b(4)

Appendix G: **Natural Ingredients/Herbal Medicines not likely to be written as a prescription**

Proprietary Name	Similarity to Colcrys	Description
Colchica (boxus colchica), also known as 'Boxwood' or SPV 30	Look	Natural ingredient used for the treatment of HIV/AIDS (said to boost immunity), arthritis, and is also used as a 'blood detoxifying agent'. Route of administration is oral; usual dose of SPV 30 for AIDS is 330 mg orally every 8 hours.

Appendix H: Products with no numeric overlap in strength, dose, and route of administration.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Colcrys (tapentadol)	N/A	Tablets: 0.6 mg	0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.
Calcijex (calcitriol)	Look	Injection: 1 mcg/mL; 2 mcg/mL	1 mcg to 2 mcg, intravenously 3 times per week
Procrit (epoetin alpha)	Sound	Injection: 2,000 units/mL; 3,000 units/mL; 4,000 untis/mL; 10,000 units/mL; 20,000 units/mL; 40,000 units/mL	150 units/kg to 300 units/kg subcutaneously 3 times per week, or 40,000 to 60,000 units once a week

Appendix I: Products with a single strength but have multiple differentiating product characteristics

Product name with potential for confusion	**Similarity to Proposed Proprietary Name**	**Strength**	**Usual Dose (if applicable)**	**Other differentiating product characteristics (Colcrys vs. potentially confusing name)**
Colcrys (Colchicine) Tablets	**N/A**	**0.6 mg**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**	**N/A**
CoLyte (polyethylene glycol-electrolyte solution)	Look	PEG 3350, electrolytes	240 mL (8 oz) every 10 minutes, until 4 L are consumed or the rectal effluent is clear	*Dose:* 0.3 mg to 1.2 mg once or twice daily vs. 8 oz *Frequency:* Once or twice daily vs. every 10 minutes until 4 Liters is consumed *Duration of therapy:* Continuous plus additional dose(s) for acute gout flare vs. one time regimen
Colazal (balsalazide disodium)	Look	750 mg	3 capsules 3 times per day for up to 8 weeks	Dose: 0.3 mg to 1.2 mg once or twice daily vs. 3 capsules Frequency: Once or twice daily vs. 3 times per day

Appendix J: Potential confusing name with numeric overlap in strength or dose

Colcrys **(Colchicine)**	**0.6 mg tablets**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**
Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects** **(Colcrys vs. potentially confusing name)**
Clorpres (chlorthalidone and clonidine) ANDA 71-323 Strengths: 15 mg/0.1 mg 15 mg/0.2 mg 15 mg/0.3 mg Frequency: once or twice daily Route: oral	Look-alike and Sound-alike Similar length of names (7 vs. 8 letters) Both names begin with 'C' and end with 's'. Each name has 2 upstrokes, 1 downstroke, no dotted letters, and no cross-strokes Each name has 2 syllables First syllable of both names has a 'hard C' plus an 'l' sound. 'ys' and 'es' sound alike when spoken Dosage form: tablets Route of administration: oral Frequency: once or twice daily Potential numeric overlap in strength [0.3 mg (1/2 tablet) of Colcrys vs. 0.3 mg component of the Clorpres 15 mg/0.3 mg strength tablet.	Medication errors unlikely to occur because Clorpres is available in three different strengths. *Rationale:* The potential for overlap exists if the strength for Clorpres is written simply as '0.3 mg', which refers to the clonidine component that is the ingredient in Clorpres that varies between the 3 product strengths. However, this is unlikely to occur since Clorpres is a combination product that is available on 3 different strengths and it is more likely that the entire strength will be written on a prescription (e.g., '15 mg/0.3 mg' or '15/3'). Additionally, a 0.3 mg dose (1/2 tablet) of Colcrys would most likely be prescribed only in a small number of pediatric patients being treated for the Familial Mediterranean Fever (FMF) orphan indication. The population that would most likely be prescribed Clorpres 15 mg/0.3 mg would be adults with hypertension. Safety and effectiveness in pediatric patients has not been established; thus, if a prescription for Colcrys 0.3 mg is misinterpreted as 'Clorpres 15 mg/0.3 mg' or 'Clorpres 0.3 mg', this would likely result in the dispensing pharmacist contacting the prescriber, since Clorpres is not approved in the pediatric population and there are no guidelines for dosage and administration.

Colcrys **(Colchicine)**	**0.6 mg tablets**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**
Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects** **(Colcrys vs. potentially confusing name)**
Coldmist JR (pseudoephedrine 48 mg/guaifenesin 595 mg)	Sound-alike Same prefix 'Col' in both names Suffixes 'crys' and 'mist' rhyme. Dosage form: tablet Frequency: once or twice daily Route of administration: oral Potential for overlap in dose since both products are single-strength and may be written as '1 tablet'.	Medication errors are unlikely to occur in the usual practice setting because this product is an unapproved drug that is no longer being marketed, therefore, it is unlikely that it is still being prescribed. However, if it were prescribed, orthographic and phonetic differences in the names would minimize the potential for an unapproved generic product to be dispensed in its place. *Rationale:* The risk for medication error is minimized by orthographic differences in the names (Colcrys vs. Coldmist JR). Upstrokes: 2 vs. 4 Downstrokes: 1 vs. zero Cross-strokes: zero vs. 1 Dotted letters: zero vs. 1 Addition of the modifier 'JR" for Coldmist differentiates the name from Colcrys orthographically and phonetically, and it is likely that a modifier would be used if Coldmist were to be prescribed because 'Coldmist' is a family trade name and the particular product would need to be specified on the prescription. Orthographically, Coldmist JR is differentiated from Colcrys which does not have a modifier. Phonetically, the modifier 'JR', when spoken, is 'junior' which adds two syllables to the name Coldmist for a total of 4 syllables vs. 2 syllables in the name, Colcrys. <u>Notes:</u> Coldmist JR was an unapproved marketed product and Clinical Pharmacology Online lists this product as 'off market'. This product is not listed in the Red Book. Two other unapproved generic products (same strength as Coldmist JR) are listed as 'off market' in Clinical Pharmacology Online, and are not listed in the Red Book. Two unapproved products,"GFN 595/PSE 48 Extended-Release Tablet (Cypress Pharmaceutical Inc) and Pseudo GG TR 595mg-48mg Extended-Release Tablet (Boca Pharmacal Inc), are ***not*** listed as 'off market' in Clinical Pharmacology Online. These products are both listed in the Red Book, thus may be available for purchase by pharmacies.

Colcrys **(Colchicine)**	**0.6 mg tablets**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**
Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects** **(Colcrys vs. potentially confusing name)**
Coldmist LA (pseudoephedrine 85 mg/guaifenesin 795 mg)	Sound-alike Same prefix 'Col' in both names Suffixes 'crys' and 'mist' rhyme. Dosage form: tablet Frequency: once or twice daily Route of administration: oral Potential for overlap in dose since both products are single-strength and may be written as '1 tablet'.	Medication errors are unlikely to occur in the usual practice setting because this product is an unapproved drug that is no longer being marketed, therefore, it is unlikely that it is still being prescribed. If it were prescribed, orthographic and phonetic differences in the names would minimize the potential for an unapproved generic product to be dispensed in its place. *Rationale:* The risk for medication error is minimized by orthographic and phonetic differences in the names (Colcrys vs. Coldmist LA). Upstrokes: 2 vs. 4 Downstrokes: 1 vs. zero Cross-strokes: zero vs. 1 Dotted letters: zero vs. 1 Addition of the modifier 'LA" for Coldmist differentiates the name from Colcrys orthographically and phonetically, and it is likely that a modifier would be used if Coldmist were to be prescribed because 'Coldmist' is a family trade name and the particular product would need to be specified on the prescription. Orthographically, Coldmist LA is differentiated from Colcrys which does not have a modifier. Phonetically, the modifier 'LA', when spoken, is either 'L-A' or 'long-acting' which adds two or three syllables to the name Coldmist for a total of 4 to 5 syllables vs. 2 syllables in the name, Colcrys. <u>Notes:</u> This is an unapproved marketed product that is listed as 'off market' by Clinical Pharmacology Online. This product is not listed in the Red Book. Four unapproved generic products (same strength/same ingredients) are also listed as 'off market' in Clinical Pharmacology Online, and are not listed in the Red Book. One unapproved product "Guaifenex PSE-85 (same strength as Coldmist LA) is made by Ethex Corporation, and is ***not*** listed as 'off market'. This products is listed in the Red Book, thus may be available for purchase by pharmacies.

Colcrys **(Colchicine)**	**0.6 mg tablets**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**
Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects** **(Colcrys vs. potentially confusing name)**
Colrex 'Compound' (APAP mg 325 mg, chlorpheniramine 2 mg, codeine 16 mg, phenylephrine 10 mg). DEA Schedule III Product listed as 'Colrex Compound' in most sources, including the NDC Directory Dosage form: capsule Route of administration: oral Frequency: unknown	Look and Sound-alike Same suffix 'Col' Similar name length (7 vs. 6 letters) Route of administration: oral Potential for overlap in dose since both products are single-strength and may be written as '1 tablet'.	Medication errors are unlikely to occur due to orthographic differences in the names and questionable availability of this product in the U.S. market. *Rationale:* Downstrokes: 1 vs. zero Crossed letters: zero vs. 1 ('x') 'Compound' follows Colrex as part of the trade name which helps to differentiate it from Colcrys, both orthographically and phonetically. Notes: Unapproved, marketed product. Very little information on this product was found in commonly used literature references. The availability of this product in the U.S. is unclear. Clinical Pharmacology Online lists the manufacturer of this product as Numark Laboratories, Inc. (Edison, NJ). Numark was contacted and they denied that Colrex Compound was their product. The NDC number is: **NDC: 55499-0840-01** This drug product is not listed in the Red Book.

Colcrys **(Colchicine)**	**0.6 mg tablets**	**0.3 mg to 1.2 mg orally, once or twice daily, without regard to meals.**
Failure Mode: **Name confusion**	**Causes** **(could be multiple)**	**Effects** **(Colcrys vs. potentially confusing name)**
Ciltyri *** (eplivanserin hemifumarate) 5 mg tablet Route of administration: oral Frequency: once daily in the evening with or without food	Look-alike: 'Col' looks like 'Cil' when scripted Names are the same length (both have 7 letters) Both have 1 downstroke 'y' in the second half of the name Both are single-strength products, thus there is a potential for overlap in dose (i.e., '1 tablet') Same frequency possible if Colcrys is prescribed as once daily and the administration time is specified as 'evening'. Same route of administration (oral) Same dosage form (tablet)	Orthographic and phonetic differences, in addition to differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. *Rationale*: The risk for medication error is minimized by orthographic and phonetic differences between the two names. Orthographic differences: 1 upstroke vs. 2 upstrokes, no cross-strokes vs 1 cross-stroke, no dotted letters vs 2 dotted letters. The last 4 letters of each name ('crys' vs. 'tyri) look different when scripted. Phonetic differences: Prefix 'Col' in Colcrys has a 'hard C' sound, while the prefix 'Cil" in Ciltyri has a 'soft C' sound. Colcrys has 2 syllables, Ciltyri has 3 syllables Neither the prefix nor the suffix of Colcrys rhyme with either the prefix, infix, or suffix of Ciltyri. Product Characteristics: When specified, the tablet strengths differentiate these two products (0.6 mg vs. 5 mg) Colcrys will typically be prescribed as once or twice daily, while Ciltyri will typically be prescribed as once daily in the evening. When Colcrys is prescribed as once daily, it is not likely that the prescriber will specify that the dose be given in the evening.

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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:	December 5, 2008
To:	Bob Rappaport, MD, Director Division of Analgesia, Anesthesia, and Rheumatology Products
Through:	Kristina Arnwine, Pharm.D., Acting Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
From:	Lori Cantin, R.Ph., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Colstat (Colchicine Tablets USP) 0.6 mg
Application Type/Number:	NDA 22-352 NDA 22-351
Submission Number:	N-000 TN N-000
Applicant:	United Research Laboratories, Inc. Mutual Pharmaceutical Company, Inc.
OSE RCM #:	2008-1643 2008-1838

1 INTRODUCTION

This review is in response to the following requests for a review of the proposed proprietary name, Colstat:

- NDA 22-352, October 8, 2008, request for consultation
- NDA 22-351, November 19, 2008, request for consultation

2 MATERIAL REVIEWED

The Division of Medication Error Prevention reviewed the list of United States Adopted Names (USAN) stems on October 20, 2008, available at: www.ama-assn.org/ama/pub/category/4782.html.

3 DISCUSSION

During the initial steps of the proprietary name review process, the Division of Medication Error Prevention and Analysis identified a safety concern with the proposed proprietary name, Colstat. The proposed proprietary name, Colstat, contains the USAN stem '-stat'. The USAN definition of the stem '-stat' is 'enzyme inhibitors'. Since COLSTAT is not an enzyme inhibitor, the use of this stem in the proposed proprietary name is inconsistent with the USAN definition.

The goal of the USAN program is to provide meaningful, informative designations for compounds, enhancing correct prescribing practices and patient safety. The listing of USAN stems represents common stems for which chemical and/or pharmacologic parameters have been established. These stems and their definitions, approved by the USAN Council, are recommended for use in coining new nonproprietary names for drugs that belong to an established series of related agents. By adopting this system, similar compounds maintain a common "family" name that provides immediate recognition.

Use of these stems in proprietary names can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names, and FDA recommends that applicants screen potential proprietary names against the USAN stem list, and eliminate those that would incorporate USAN stems.

While DMEPA recognizes that there are approved drug products that contain the USAN stem "-stat" in the proprietary name, we note that we did not review the majority of these names. Prior to the FDA recommendation against the use of USAN stems in proprietary names it is possible that DMEPA may have reviewed and found names containing USAN stems to be acceptable. However, moving forward, our goal is to minimize the potential for name confusion by not approving proprietary names that contain a USAN stem which may be confused with established names that contain the same USAN stem. Therefore, the Division of Medication Error Prevention and Analysis will object to the use of a proposed proprietary name when the proposed proprietary name contains a USAN stem.

4 CONCLUSIONS AND RECOMMENDATIONS

The Division of Medication Error Prevention and Analysis objects to the use of the proposed proprietary name, Colstat, since it contains the USAN stem "-stat"; therefore, we will not proceed with a full review for this name. The Applicant should submit an alternative proposed proprietary name for the drug product, Colchicine, for review.

If you have any questions or need clarifications, please contact Chris Wheeler, OSE Project Manager, at (301) 796-0558.

4.1 COMMENTS TO THE APPLICANT

We have completed our review of this proposed proprietary name and have concluded that the name COLSTAT is unacceptable because it contains the United States Adopted Names (USAN) Council stem '-stat'. USAN stems are intended to indicate a pharmacological or chemical trait of a drug. The USAN definition of the stem '-stat' is 'enzyme inhibitors'. Since COLSTAT is not an enzyme inhibitor, the use of this stem in the proposed proprietary name is inconsistent with the USAN definition.

The USAN Council (tri-sponsored by the American Medical Association (AMA), the United States Pharmacopeial Convention (USP), and the American Pharmacists Association (APhA)) works closely with the International Nonproprietary Name (INN) Programme of the World Health Organization (WHO) and various national nomenclature groups to achieve global standardization and unification of drug nomenclature and related rules with the goal of ensuring that drug information is communicated accurately and unambiguously.

Use of these stems in proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names we recommend you screen potential proprietary names against the USAN stem list, and eliminate those that would incorporate USAN stems.

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