CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204061Orig1s000

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
Office of Medication Error Prevention and Risk Management

Proprietary Name Review--Final

Date:	January 7, 2013
Reviewer:	Manizheh Siahpoushan, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Zachary Oleszczuk, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Quartette (Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.02 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.025 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.03 mg, and Ethinyl Estradiol 0.01 mg Tablets)
Application Type/Number:	NDA 204061
Applicant/sponsor:	Teva Pharmaceuticals
OSE RCM #:	2012-2809

*** This document contains proprietary and confidential information that should not be released to the public.***

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Quartette is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Quartette, acceptable in OSE Review 2012-1420 dated September 10, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-1420. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our re-evaluation did not alter our conclusion for OSE Review 2012-1420. The searches of the databases did not yield any new names thought to look or sound similar to Quartette and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 1, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on January 7, 2013 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Quartette, did not identify any vulnerabilities that would result in medication errors with any additional name(s) noted in this review. Thus, DMEPA has no objection to the proprietary name, Quartette, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Reproductive and Urologic Products (DRUP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Marcus Cato, OSE project manager, at 301-796-3903.

4 REFERENCES

1. OSE Review #2012-1420, Proprietary Name Review of Quartette (Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol; Siahpoushan, M. September 10, 2012.

2. 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.

3. USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?)

USAN Stems List contains all the recognized USAN stems.

4. Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MANIZHEH SIAHPOUSHAN
01/07/2013

ZACHARY A OLESZCZUK
01/07/2013

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
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Proprietary Name Review

Date:	September 10, 2012
Reviewer:	Manizheh Siahpoushan, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Zachary Oleszczuk, PharmD Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Quartette (Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.02 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.025 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/0.03 mg, and Ethinyl Estradiol 0.01 mg Tablets)
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1 INTRODUCTION

This review evaluates the proposed proprietary name, Quartette, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Teva Pharmaceuticals submitted a request for proprietary name review of Quartette for Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/ 0.02 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/ 0.025 mg, Levonorgestrel/Ethinyl Estradiol Tablets 0.15 mg/ 0.03 mg and Ethinyl Estradiol 0.01 mg Tablets (NDA 204061), on June 18, 2012. This name was found acceptable in OSE Review# 2010-401, dated July 26, 2010 for IND 072290. Additionally, the Applicant submitted labels and labeling in the original NDA submission, dated May 31, 2012 which will be reviewed under a separate cover in OSE Review #2012-1425.

1.2 PRODUCT INFORMATION

The following product information is provided in the June 18, 2012 proprietary name submission.

- Active Ingredient: Levonorgestrel and Ethinyl Estradiol
- Indication of Use: Prevention of pregnancy
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg
- Dose and Frequency: One tablet orally at the same time every day.
- How Supplied: Each cycle pack will be packaged in a tri-fold, perforated, white blister card where each of the first two parts has 28 combination pills and the third part has 28 combination pills and 7 Ethinyl Estradiol pills (35 pills total) for each 91 day cycle. Each tri-fold blister pack will be sealed in a foil pouch. Physician samples will be provided with the same configuration.
- Storage: 20°C to 25°C (68°F to 77°F)
- Container and Closure Systems: The primary packaging components that come in contact with the tablets are the (b) (4) blister film and the push-through aluminum foil. The blister film is (b) (4) oisture protection. The push through blister lidding foil is a (b) (4) aluminum foil that is printed on both sides. Each 91-day regimen contains 3 blister cards which are placed into a single (b) (4) compact and sealed in a foil pouch containing a 2g (b) (4) desiccant and patient leaflet. Sealed pouches are then placed in a cardboard carton.
- Pronunciation: Kwor-tet

2. RESULTS

The following sections provide the information obtained and considered in the evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive and Urology Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) SEARCH

The June 20, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Quartette, is an extended regimen oral contraceptive that consists of a 91 day regimen four times a year. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Seventeen practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Ten out of seventeen participants interpreted the name correctly as 'Quartette' (5 in inpatient and 5 in outpatient prescription studies). One participant in the voice prescription studies misinterpreted the name incorrectly as 'Cortet' and six participants omitted the ending letter string '-te' (i.e. 'Quartet'). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, June 29, 2012 e-mail, the Division of Reproductive and Urology Products (DRUP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Quartette. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Quartette identified by the primary reviewer (PR) and the Expert Panel Discussion (EPD).

Table 1: Collective List of Potentially Similar Names (DMEPA and EPD)

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Quadramet	EPD	Activella	EPD, PR	Azurette	EPD
Quartuss	EPD, PR	Mircette	EPD, PR	Questran	EPD, PR
Quelicin	EPD	Quintabs	EPD	Nordette-28	EPD, PR
Oxacillin	EPD	Ovrette	PR	(b) (4) ***	PR
Emoquette	EPD	Aranelle	PR	Quinaretic	PR
Nicorette	PR				
Sound Similar					
Cortef	PR				
Look and Sound Similar					
Quartette	EPD				

Our analysis of the 18 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 18 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Reproductive and Urology Products via e-mail on July 5, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Reproductive and Urology Products on July 5, 2012, they stated no additional concerns with the proposed proprietary name, Quratette.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. The Applicant will be notified of this finding via letter with the comments provided in the Section 3.1.

If you have further questions or need clarifications, please contact Marcus Cato, OSE project manager, at 301-796-3903.

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3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Quartette, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your June 18, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

4 REFERENCES

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

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

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

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. 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.

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

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the 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. ***U.S. Patent and Trademark Office (http://www.uspto.gov)***

   USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)***

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***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.

10. ***Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

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

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book (www.thomsonhc.com/home/dispatch)***

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

14. ***Lexi-Comp (www.lexi.com)***

    Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations (www.medilexicon.com)***

    Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy (www.CVS.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

17. ***Walgreens (www.walgreens.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

18. ***Rx List (www.rxlist.com)***

    RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. ***Dogpile (www.dogpile.com)***

    Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. ***Natural Standard (http://www.naturalstandard.com)***

    Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). 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]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because 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.

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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.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, 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. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. 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.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing 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). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

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

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/Similar shape Upstrokes Down strokes Cross-strokes 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

Lastly, DMEPA considers the potential for the proposed proprietary 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. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches 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 the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA 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 reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name 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 healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions 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 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 record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment 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.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause 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 orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

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

characteristics listed in Section 1.2 of this review. 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 Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. 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, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes 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 not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name 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 the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP'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 PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. 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)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, 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 but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, 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, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, 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.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Quartette	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'Q'	'O', 'A'	'K', 'C'
Lower case 'q'	'y', 'g', 'j', 'z'	'K', 'C'
Lower case 'u'	'a', 'o', 'i', 'll', 'n', 'y', 'v', 'w'	Any vowel
Lower case 'a'	'o', 'e', 'u', 'cl', 'd', 'ci'	Any vowel
Lower case 'r'	'n', 'i', 's', 'e', 'v'	'wr'
Lower case 't'	'l', 'f', 'x', 'r', 'A'	'd'
Lower case 'e'	'a', 'i', 'o', 'u', 'l'	Any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Quartette Study (Conducted on 6/29/12)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Quartette 1 po qday	Quartette One tablet by mouth daily #1
Outpatient Prescription: Quartette 1 PO Qday #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

17 People Responded

Study Name: Quartette

Total	5	7	5	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CORTET	0	1	0	1
QUARTET	0	6	0	6
QUARTETTE	5	0	5	10

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Quartette	Failure preventions
Ovrette	Norgestrel 0.075 mg	Look	Application withdrawn pending Federal Register Notice- 4/30/07. There are no generic equivalents marketed. Additionally, the name pair has sufficient orthographic and /or phonetic differences.
(b) (4) ***	Norethindrone and Ethinyl Estradiol	Look	NDA 022573, name was found unacceptable in OSE Review #2010-929, dated July 27, 2010; however the product was approved on 12/22/10 without a proprietary name. Additionally, the name pair has sufficient orthographic and /or phonetic differences.
Quartette	Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol	Look and sound	Proprietary name under analysis in this review.

***

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Questran (Cholestyramine) Powder for Oral Suspension Usual Dose: The recommended starting adult dose is one packet or one level scoopful once or twice a day. The recommended maintenance dose is 2 to 4 packets or scoopfuls daily (8-16 grams anhydrous cholestyramine resin) divided into two doses.	Orthographic: Both names share the beginning letter string 'Qu-' followed by letter strings that appear similar when scripted ('-ar-' vs. '-es-'), and the upstroke 't' in the fifth position Route of Administration: Oral Strength: Single strength Overlap in the Frequency of Administration: Once a day Overlap in the Usual Dose: One (tablet vs. packet)	Orthographic: The letter string '-ette' in Quartette does not appear similar to the letter string '-ran' in Questran and can help differentiate Quartette and Questran when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Cortef (Hydrocortisone) Tablets 5 mg, 10 mg, 20 mg Usual Dose: 20 mg to 240 mg orally daily.	Orthographic/Phonetic: The similarly positioned letter strings '-artet-' in Quartette and '-ortef' in Cortef appear similar when scripted. Phonetically, both names consist of 2 similar sounding syllables which would make it difficult to differentiate the two names when spoken ('Quar' vs. 'Cor' and 'tette' vs. 'tef'). Route of Administration: Oral Dosage Form: Tablets Frequency of Administration: Once daily Overlap in the Usual Dose: One tablet	Orthographic: The additional letter 'u' in the second position and the letter string '-te' at the end of the name, Quartette, provide a longer appearance for this name which can help differentiate Quartette and Cortef when scripted. Strength: Single strength vs. multiple strengths (5 mg, 10 m, and 20 mg). Therefore, the strength must be provided on both written and verbal orders for Cortef. Orders for the single strength product, Quartette, may not include the strength especially because the strength is complex and it is not required to dispense the product. Thus, the risk of confusion between these two phonetically similar names is minimized.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Quartuss (Chlorpheniramine Maleate, Dextromethorphan Hydrobromide, Guaifenesin and Phenylephrine) Oral Syrup 15 mg, 2 mg, 10 mg, 100 mg/5 mL Usual Dose: Two teaspoonfuls (10 mL) orally every 6 hours. Quartuss DM (Chlorpheniramine Maleate, Dextromethorphan Hydrobromide, Phenylephrine Hydrochlorde) Oral Drops/Solution 3 mg, 1.5 mg, 1 mg/mL Usual Dose: Adults and Adolescents: 5 mL orally every 4 hours as needed. Children 6 to 12 years: 2.5 mL orally every 4 hours as needed.	Orthographic: Both names share the letter string 'Quart-' in the same position of each name followed by similarly scripted vowels ('e' vs. 'u'). Route of Administration: Oral Strength: Single strength Numerical Overlap in the Usual Dose: One (tablet vs. teaspoonful)	Orthographic: The ending letter string '-tte' in Quartette does not appear similar to the ending letter string '-ss' in Quartuss which can help differentiate Quartette and Quartuss when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Activella (Estradiol and Norethindrone Acetate) Tablets 1 mg/0.5 mg and 0.5 mg/0.1 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names consist of 9 letters, share similarly scripted ending letter strings (‘-ette’ vs. ‘-ella’) and beginning letter strings (‘Qu-‘ vs. ‘Ac-‘, and the upstroke ‘t’. Route of Administration: Oral Dosage Form: Tablets Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The letter string ‘-ar-‘ in Quartette (i.e. longer length between ‘Q’ and ‘t’ in Quartette vs. ‘A’ and ‘t’ in Activella) and the letter string ‘-iv-‘ in Activella (shorter length between ‘t’ and ‘t’ in Quartette vs. ‘t’ and ‘l’ in Activella) provide different shapes for the name pair and can help differentiate them when scripted. Strength: Single strength vs. multiple strengths (1 mg/0.5 mg and 0.5 mg/0.1mg)

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Mircette (Desogestrel and Ethinyl Estradiol and Ethinyl Estradiol) Tablets, 0.15 mg/0.02 mg and 0.01 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names share the ending letter string '-ette'. Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The letter string 'Quart-' does not appear similar to the letter string 'Mirc-' which can help differentiate Quartette and Mircette when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Nordette-28 (Levonorgestrel and Ethinyl Estradiol) Tablets 0.15 mg/0.03 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names share the ending letter string '-ette' and similarly scripted letter strings in similar positions of each name ('-art-' vs. '-ord-'). Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The beginning letter 'Q' does not appear similar to the beginning letter 'N' and can help differentiate Quartette and Nordette when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Emoquette (Desogestrel and Ethinyl Estradiol) Tablets 0.15 mg/0.03 mg Usual Dose: One tablet orally once daily	Orthographic: Both names share the ending letter string '-ette'. Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The letter string 'Quart-' does not appear similar to the letter string 'Emoqu-' when scripted and can help differentiate the two names orthographically.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Aranelle (Norethindrone and EThinyl Estradiol) Tablets 0.5 mg/0.035 mg; 1 mg/0.035 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names share similar scripted ending letter strings (‘-ette’ vs. ‘-elle’, beginning letters (‘Q’ vs. ‘A’ scripted in lower case), and similarly positioned letter strings (‘-ar-‘ vs. ‘-an-‘). Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The upstroke ‘t’ in the fifth position of the name, Quartette, provides a different shape for this name which can help differentiate Quartette and Aranelle when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Quinaretic (Quinapril Hydrochloride and Hydrochlorothiazide) Tablets 10 mg/12.5 mg, 20 mg/12.5 mg, 20 mg/25 mg Usual Dose: One tablet orally once daily. The product name, Quinaretic is discontinued; however, generic equivalents are marketed.	Orthographic: Both names share the beginning letter string 'Qu-' followed by similar scripted letter strings ('-ar-' vs. '-in-'). Additionally, both names share the upstroke 't' in the eighth position of each name followed by similar scripted vowels ('e' vs. 'i'). Route of Administration: Oral Dosage Form: Tablets Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The two upstrokes (i.e. 't') in the fifth and seventh position of Quartette provide a different shape for this name and can help differentiate Quartette and Quinaretic when scripted. Strength: Single strength vs. multiple strengths (10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg)

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Nicorette (Nicotine Polacrilex) Chewing Gum, 2 mg, 4 mg Usual Dose: Weeks 1 to 6: 1 piece of gum every 1 to 2 hours Weeks 7 to 9: 1 piece of gum every 2 to 4 hours Weeks 10 to 12: 1 piece of gum every 4 to 8 hours Strength is dependent upon number of cigarettes smoked per day	Orthographic: Both names consist of 9 letters and share the ending letter string '-ette'. Route of Administration: Oral Dosage Form: Solid oral Overlap in the Usual Dose: One (tablet vs. gum)	Orthographic: The letter string 'Quart-' in Quartette does not appear similar to the letter string 'Nicor-' in Nicorette when scripted and can help differentiate Quartette and Nicorette orthographically.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Azurette (Desogestel and Ethinyl Estradiol) Tablets 0.15 mg/0.02 mg Usual Dose: One tablet orally once daily.	Orthographic: Both names share the letter string '-ette', similar scripted beginning letters ('O' vs. 'A' when scripted in lower case 'a') followed by similar scripted letter strings in each name ('-uar-' vs. '-zur-' if the letter 'z' is not scripted as a lower case). Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The fifth position letter 't' in Quartette provides a different shape and a longer length for this name and can help differentiate Quartette and Azurette when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Quelicin (Succinylcholine Chloride) Injection 200 mg and 1000 mg Usual Dose: The optimum dose will vary among individuals and may be from 0.3 to 1.1 mg/kg for adults. 2 to 3 mg/kg in neonates and infants to 6 months and 1to 2 mg/kg in infants up to 2 years of age.	Orthographic: Both names share the beginning letter string 'Qu-' followed by similar scripted vowels ('a' vs. 'e'), and an upstroke ('t' vs. 'l') in similar positions (fifth vs. fourth) followed by similar scripted vowels ('e' vs. 'i'). Possible Numerical Overlap in the Usual dose: Since weight based, the calculated dose of Quelicin may be 60 mg.	Orthographic: The ending letter string '-tte' in Quartette does not appear similar to the ending letter string '-cin' in Quelicin and can help differentiate Quartette and Quelicin when scripted. Strength: Single strength vs. multiple strengths (200 mg and 1000 mg)

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Quintabs (Multivitamin including A, D, E, B, C, and Folate) Tablets Usual Dose: One tablet orally once daily or as directed.	Orthographic: Both names share the beginning letter string 'Qu-' and similar scripted letter strings in the same position of each name ('-rte-' vs. '-nta-'). Route of Administration: Oral Dosage Form: Tablets Strength: Single strength Frequency of Administration: Once daily Usual Dose: One tablet	Orthographic: The ending letter string '-tte' in Quartette does not appear similar to the ending letter string '-bs' in Quintabls and can help differentiate Quartette and Quintabs when scripted.

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Oxacillin (Oxacillin Sodium) Injection 10 grams Usual Dose: Adults: 250 to 500 mg intravenously every 4 to 6 hours (mild to moderate infections) and 1 gram every 4 to 6 hours for severe infections. Infants and children less than 40 kg: 50 mg/kg/day intravenously in equally divided doses every 6 hours (mild to moderate infections) and 100 mg/kg/day in equally divided doses every 4 to 6 hours (severe infections)	Orthographic: Both names consist of 9 letters, share similar scripted beginning letters ('Q' vs. 'O'), letter 'a' in the third position of each name, two upstrokes in similar positions (seventh and eighth vs. sixth and seventh) followed by similar scripted vowels ('e' vs. 'i'). Strength: Single strength Possible Numerical Overlap in the Usual Dose: One (tablet vs. gram)	Orthographic: The fifth position upstroke 't' in Quartette and the ending letter 'n' in Oxacillin provide different shapes for each of these names and can help differentiate Quartette and Oxacillin when scripted. .

Proposed name: Quartette **(Levonorgestrel/Ethinyl Estradiol and Ethinyl Estradiol)** **Dosage Form(s): Tablets** **Strength: 0.15 mg/0.02 mg, 0.15 mg/0.025 mg, 0.15 mg/0.03 mg and 0.01 mg** **Usual Dose: One tablet orally once daily.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
Quadramet (Samarium sm 153 lexidronam) Injection Usual Dose: The recommended dose is 1 mCi/kg, administered intravenously over a period of one minute through a secure in-dwelling catheter and followed with a saline flush	Orthographic: Both names share the beginning letter string 'Qua-' and similar position (fifth vs. fourth) upstrokes ('t' vs. 'd'). Strength: Single strength Overlap in the Frequency of Administration: Once Possible Numerical Overlap in the Usual Dose: The calculated dose of Quadramet may be 60 mCi/kg	Orthographic: The different appearance of the ending letter strings in each name ('-ette' vs. '-amet' can help differentiate Quartette and Quadramet when scripted.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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