CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022532Orig1s000

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:	August 13, 2010
Application Type/Number:	NDA 022532
Through:	Melina Griffis, R.Ph, Team Leader Denise P. Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis
From:	Richard A. Abate, RPh, MS Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Beyaz (Drospirenone, Ethinyl Estradiol, Levomefolate Calcium Tablets and Levomefolate Calcium Tablets) 3 mg/0.02 mg/0.451 mg and 0.451 mg
Applicant:	Bayer Healthcare Pharmaceuticals
OSE RCM #:	2010-1161

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Beyaz, 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, Beyaz, acceptable in OSE Review # 2009-2462 dated March 9, 2010. DDMAC reviewed the proposed name on June 16, 2010 and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the review Division did not have any concerns with the proposed name, Beyaz, during our initial review.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff search 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. We used the same search criteria used in OSE Review # 2009-2462 for the proposed proprietary name, Beyaz. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases did not yield any new names thought to look or sound similar to Beyaz and represent a potential source of drug name confusion. Additionally, DMEPA staff did not identify any USAN stems in the proposed proprietary name, Beyaz, as of July 29, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The re-review of the proposed proprietary name, Beyaz, did not identify any additional names thought to look or sound similar to the proposed name since our last review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Beyaz, 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 should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. OSE reviews # 2009-2462, Proprietary Name Review Beyaz, March 9, 2010, Abate, R.

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/category/4782.html)

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.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22532	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	YAZ Folate

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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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08/13/2010

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08/13/2010

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08/13/2010

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:	March 9, 2010
To:	Scott Monroe, MD, Director Division of Reproductive and Urology Products
Through:	Melina Griffis RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Richard Abate, RPh, MS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Beyaz (Drospirenone, Ethinyl Estradiol and Levomefolate Calcium) 3 mg/0.02 mg/0.451 mg Tablets
Application Type/Number:	NDA 022532
Applicant:	Bayer Healthcare
OSE RCM #:	2009-2462

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

CONTENTS

EXECUTIVE SUMMARY

Beyaz is the proposed proprietary name for Drospirenone, Ethinyl Estradiol and Levomefolate Calcium tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Bayer Healthcare. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Beyaz conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Bayer Healthcare on December 16, 2009 for an assessment of the proposed proprietary name, Beyaz, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study in support of their proposed proprietary name. The Labels and Labeling included in this submission were reviewed separately in OSE review # 2009-1841.

1.2 REGULATORY HISTORY

The Applicant submitted the proposed proprietary name, (b) (4), for NDA 022532 on September 25, 2009. DMEPA objected to this proposed name for several reasons which were communicated to the Applicant in a teleconference November 19, 2009. Based on this teleconference, the Applicant withdrew this name and submitted alternative proprietary names for this product with Beyaz as the primary choice.

1.3 PRODUCT INFORMATION

Beyaz (Drospirenone/Ethinyl Estradiol/Levomefolate Calcium) is combination oral contraceptive tablet which is indicated for prevention of pregnancy, treatment of symptoms of premenstrual dysphoric disorder (PMDD), and treatment of moderate acne for women of at least 14 years old. In addition, Beyaz includes levomefolate, a folic acid derivative, to improve the folate status of women receiving this product. Beyaz is packaged as 28 tablets in blister cards (24 pink tablets containing 3 mg drospirenone, 0.02 mg ethinyl estradiol and 0.451 mg of levomefolate calcium plus 4 light orange tablets containing 0.451 mg levomefolate calcium). The tablets are arranged in four rows of seven tablets. Beyaz tablets are to be taken by mouth daily in the sequence outlined on the blister card unit. Beyaz is available in cartons containing three units of 28 tablets for retail use and cartons containing 5 units of 28 tablets for physician samples. Beyaz is stored at room temperature.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, and 2.3 identify specific information associated with the methodology for the proposed proprietary name, Beyaz.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'B' 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.[1,2]

To identify drug names that may look similar to Beyaz, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (five letters), upstrokes (two, capital letter, 'B' and 'Y'), down strokes (two, lower case 'y' and 'z'), cross strokes (none), and dotted letters (none). (b) (4) Additionally, several letters in Beyaz may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Beyaz or (b) (4).

When searching to identify potential names that may sound similar to Beyaz, the DMEPA staff search for names with similar number of syllables (two), stresses (BE-yaz or be-YAZ), and placement of vowel and consonant sounds. (See Appendix B) The Applicant's intended pronunciation (bee-yaz) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

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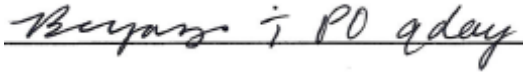
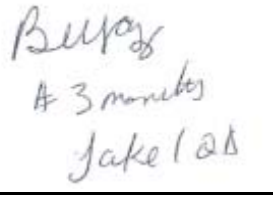
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

Figure 1. Beyaz Study (conducted on December 31, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order : 	Beyaz Take 1 QD Dispense 3 months
Outpatient prescription: 	

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Applicant submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings. After the Safety Evaluator has determined the overall risk associated with proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Applicant. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of twelve names as having some similarity to the name Beyaz.

Seven of the names were thought to look like Beyaz. These include: Bayer, BayRab, Bengay, Bepreve, Bexxar, Boyol, and Dizac. The remaining five names were thought to look and sound similar to Beyaz: Baycol, Beyaz Reyataz, Yasmin and Yaz.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 8, 2010.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Beyaz.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 PRESCRIPTION ANALYSIS STUDIES

A total of 56 practitioners responded with eight of the responses overlapping with an existing name (seven respondents as Buspar and one respondent as Boniva), which will be included in the Safety Evaluator Assessment. Twelve of the participants interpreted the name correctly as "Beyaz," with correct interpretation occurring in the all three studies. The remaining written responses misinterpreted the drug name, or the respondents were unable to interpret the prescription. We note the Outpatient sample in Figure 1 is difficult to read. In the verbal studies, all but one of the responses were misspelled phonetic variations of the proposed name, Beyaz. Although, one respondent noted the proposed name was "too similar" to Yaz. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Bayer Healthcare, (b) (4) identified no drug names thought to have some potential for confusion with the name BeYAZ. However, (b) (4) noted the similarity of the company name, Bayer as identified in Section 3.1. In addition, (b) (4) noted should a prescriber list prescriptions using an A, B, C (etc.) rather than 1, 2, 3 (etc.) the product may be confused as "B. YAZ" and YAZ may be dispensed. Yaz was also identified in Section 3.1. Thus, (b) (4) concluded BeYAZ has low vulnerability from the safety standpoint.

3.5 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator resulted in six additional names which were thought to look or sound similar to Beyaz or BeYaz and represent a potential source of drug name confusion. The names identified to have look-alike similarities are (b) (4)***, Hespan, Reglan, Repan, and Requip. The name, BSS, was identified to have sound-alike similarities.

Two names Bayer and Beyaz were not evaluated further since Bayer is not a drug name, and Beyaz was identified on the U.S. Patent and Trademark Office website registered to the Applicant likely for this product. Thus, we evaluated a total of eighteen names: two identified from the FDA Prescription Analysis Studies, six identified by the primary safety evaluator, and ten identified in section 3.1 above.

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

3.6 COMMENTS FROM THE DIVISION OF REPRODUCTIVE AND UROLOGY PRODUCTS (DRUP)

3.6.1 Initial Phase of Review

In response to the OSE, January 25, 2010 e-mail, Division of Reproductive and Urology Products (DRUP) did not forward any concerns on the proposed name at the initial phase of the name review.

3.6.2 Midpoint of Review

DMEPA notified the Division of Reproductive and Urology Products via e-mail that we had no concerns with the proposed proprietary name, Beyaz, on February 17, 2010. Per e-mail correspondence from the Division of Reproductive and Urology Products on February 19, 2010, they indicated the Division had no other issues with the proposed proprietary name, Beyaz.

4 DISCUSSION

This proposed proprietary name, Beyaz, is evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application is considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed proprietary name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the Division of Reproductive and Urology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

4.2 SAFETY ASSESSMENT

DMEPA evaluated eighteen names for their potential similarity to the proposed proprietary name, Beyaz. No other aspects of the name were considered to pose potential confusion with the name.

Failure modes and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the eighteen names and lead to medication errors. This analysis determined that the name similarity between Beyaz and all of the identified names was unlikely to result in medication error for the reasons presented in Appendices D through G.

(b) (4) identified the use of capitalized letters (e.g. A, B, C, etc.) rather than numbers for listing multiple prescriptions as creating the potential for "Beyaz" to be misinterpreted or misunderstood as "B. Yaz" resulting in the original oral contraceptive formulation to be dispensed in error. While DMEPA acknowledges that it is possible for prescribers to list medications using letters rather than numbers, it is not usual practice. Furthermore, DMEPA notes that a period, the punctuation mark, or a blank space are not orthographically similar to the letter 'e' which is part of the proposed proprietary name, Beyaz. Thus, we believe this potential source of confusion to be unlikely.

(b) (4)

This is discussed further in OSE review # 2009-184, DMEPA's Label and Labeling Review for NDA 022532.

5 CONCLUSIONS AND RECOMMENDATIONS

We have completed our review of the proposed proprietary name, Beyaz, and it is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Beyaz, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified via letter.

The proposed proprietary name, Beyaz, must be re-reviewed 90 days before approval of the NDA. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

If you have further questions or need clarifications, please contact Maria Wasilik, project manager, at 301-796-0567.

6 COMMENTS TO THE APPLICANT

6.1 PROPRIETARY NAME

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

(b) (4)

Beyaz 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.

7 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.

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

DARRTS is a government database used to organize Applicant and Applicant 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. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

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

USPTO provides information regarding patent and trademarks.

9. 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.

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)

Natural Medicines 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)

Stat!Ref contains full-text information from approximately 30 texts; it 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/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.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name 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 the Center. 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. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode

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

and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. 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.

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. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug 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.

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. Because drug name confusion can occur at any point in the medication use process, DMEPA staff 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.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies 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). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff 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. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a

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

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

variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

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 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, the DMEPA staff also 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 staff conducts searches 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 the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use 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, the DMEPA staff review 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.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). 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 DMEPA staff 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 primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. 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 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 the 123 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 DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

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, conducts a Failure Mode and Effects Analysis, and provides an overall 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.[6] 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 characteristics listed in Section one. 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?"***

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. 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.

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

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 Risk Assessment:

a. 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 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.

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 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. In that instance, DMEPA may be able to provide the Applicant 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. However, the safety concerns set forth in criteria a through e 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 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 a preventable source of medication error that, in many instances, the Agency and/or Applicant 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. Applicants have undertaken higher-leverage

strategies, such as drug name changes, 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 approving the error-prone proprietary name. Moreover, even after Applicants' 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. . (See Section 4 for 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 primary Safety Evaluator uses the FMEA process 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. In that instance, DMEPA may be able to provide the Applicant 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.

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in Name, Beyaz	Scripted may appear as	Spoken may be interpreted as
Capital 'B'	'Pr,' R	'D,' 'P,' or 'V'
lower case 'b'	h, 'le,' or 'li'	same as above
lower case 'e' pairing 'ey'	c, i, or l 'uj'	any vowel
lower case 'y'	g, 'ij,' p, q, or z	i or u
lower case 'a'	c, 'ce,' 'ci,' 'el,' or x	any vowel
lower case 'z'	j, m, r, v, or y	'c' followed by a silent 'e' or 'ss'

Appendix C: **FDA Prescription Study Responses.**

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Beyaz	?	Beaz
Biyaz	?	Diaz,
Beyaz	Bujaz	BS,
Buspar	Beejay	Biaz
Beyaz	Beyaz	Beaz ("B - Yaz" so unless it's a generic for Yaz, it's too similar)
Bupaz	Buzaz	B-Yaz
Berjaz	Bujaz	Diaz
Buspar	Belfaz	Beyaz
Beyaz	(Boniva??	B As
Beyaz	Buspar?	Beaz
Beyaz	Buspar	Biaz,
Berpaz	Buspar?	Beaz
Beyaz	Bujaz	Biaz
Buyaz	Bupaz	
Buspar	Bupaz	
Berpaz?	Bu?	
Bujaz	Bujaz	
Beyaz	?	
?	Bufoy	
Beyaz	Buspar	
Bujaz		
Birjaz		

Appendix D: Proprietary names that lack convincing orthographic and/or phonetic similarities

Proprietary Name	Similarity to Beyaz
Yasmin	Look and Sound

Appendix E: Proprietary names of products removed from the market for safety reasons

Proprietary Name	Similarity to	Active Ingredient	Action
Baycol	Look and Sound	Cerivastatin sodium	Product withdrawn from the market due to safety risks of rhabdomyolysis per Section 505 (e) of the FD&C Act, August 2001
Dizac	Look	Diazepam emulsified injection	Product withdrawn from the market due to safety risks per Section 505 (e) of the FD&C Act, September 2000

Appendix F: Risk of name confusion minimized by preventions listed. (Potential contributing causes highlighted by *italics*)

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Failure Mode of name confusion prevented by the combination of stated product characteristics as well as orthographic and/or phonetic differences as described.
Beyaz **(Drospirenone, Ethinyl Estradiol, and Levomefolate Calcium)**		**3 mg/0.02 mg/ 0.451 mg tablets** **(Strength may be omitted during prescribing and procurement steps of medication use process for single strength products.)**	**One tablet daily.** **(Dispense quantity likely to be written in number of packs or months for oral contraceptives)**	
BayRab (Rabies Immune Globulin) Discontinued product but products with the same established name and dosage form continue to be marketed This name continues to appear in online medication information databases, e.g. www.lexicomp.com	Look	2 mL and 10 mL vials containing 150 international units/mL	20 International units/kg should be infiltrated around and into the wound(s); remaining volume should be administered I.M. in the deltoid muscle of the upper arm or lateral thigh muscle.	Orthographic differences provided by an upstroke at the end of the name. Dosage form: injection vs. tablet Route of administration: subcutaneously and intramuscularly vs. oral This product is limited to Emergency Room or Clinic use
Bengay (Family trade name)	Look	Greaseless Bengay: 15% methyl salicylate, 10% menthol Ultra strength cream: 30% methyl salicylate, 10% menthol, 4% camphor Arthritis Formula:	Apply to affected area three to four times daily.	Bengay is a family name with multiple strengths and formulations, while Beyaz is available in one strength and one dosage form. Dose: a small amount vs. one tablet Dosage form: Cream, pad, and patch vs. tablet Route of administration: topical vs. oral

		30% methyl salicylate, 8% menthol Vanishing Scent: Menthol 2.5% Bengay PM: Menthol 10% Ultra strength Patch: 5% menthol Original strength patch: 1.4 % Menthol Moist Heat Therapy pads	Apply for up to eight hours in a 24 hour period.	
Bepreve (Bepostatine Besilate)	Look	1.5 % ophthalmic solution *(Single Strength)*	Allergic Conjunctivitis: One drop into affected eye twice daily.	Orthographic difference stems from the name appearing longer which is provided by an additional two letters in the name Bepreve. Dosage form: Ophthalmic solution vs. tablet. Route of administration: ophthalmic vs. tablet. Frequency of administration: twice daily vs. daily.
Bexxar (Tositumomab and Iodine 131I Tositumomab	Look	35 mg and 225 mg (14 mg/mL) Dosimetric and Therapeutic kits	450 mg intravenously once and the therapy then repeated in seven to 14 days.	Bexxar is a radioactive agents which is prescribed by radiation oncologists. The product must be prepared by a nuclear pharmacy. The specialized use of Bexxar minimizes the potential for confusion with Beyaz.
Boyol Found as Boyol Salve (Ichthamol and Benzocaine) Product no longer listed for sale on company website or 2009 Redbook, but other ichthamol topical products are marketed.	Look	10% ichthamol *(Single Strength)*	Apply *once* or twice *daily.*	Orthographic difference provided by the second part of the name (Salve) Dosage form: ointment vs. tablet Route of administration: Topical vs. oral.
BSS (Balanced Salt Solution)	Sound	none (multiple component solution for irrigation) *(Single Strength)*	500 mL irrigation during ocular surgical procedures	Phonetic difference stem from the fact BSS has three syllables vs. two in Beyaz. BSS is limited to use during surgery. Dosage form: solution for irrigation vs. tablet. Route of administration: Intraocular and extraocular vs. oral
Hespan	Look	6 %	500 mL or 1000 mL intravenously as an infusion for	Dosage form: injection vs. tablet

(Hetastarch)		(*Single Strength)*	hypovolemic shock.	Route of administration: intravenous vs. oral. Hespan is limited to use in a hospital setting for urgent or emergency patient conditions.
Reglan (Metoclopramide HCl)	Look	5 mg and 10 mg tablets 10 mg/2 mL, 50 mg/ 10 mg, and 150 mg/ 30 mL injection (vials) 5 mg/5 mL oral solution.	Gastroparesis: 10 to 15 mg by mouth four times daily (before meals and at bedtime.) Chemotherapy induced nausea and vomiting. 2 mg/kg intravenously 30 minutes prior to chemotherapy.	Orthographic difference stems from the letter 'l' in Reglan which provides an upstroke after the down stroke in the middle of the name. Strength: multiple strengths vs. single strength (none of which numerically overlap) Frequency of administration: four times daily or single dose vs. daily.
Reyataz (Atazanavir Sulfate)	Look and Sound	100 mg, 150 mg, 200 mg and 300 mg capsules	HIV infection Adults: Take 300 mg (*one* capsule) with ritonavir or 400 mg (two capsules) with ritonavir *by mouth daily* with food. Pediatric (weight based) with ritonavir 15 kg to < 25 kg: 150 mg (*one* capsule) by mouth *daily* with food. (Only for treatment naive patients.) 25 kg to < 32 kg: 200 mg (*one* capsule) by mouth *daily* with food. 32 kg to < 39 kg: 250 mg (one 100 mg capsule and one 150 mg capsule) by mouth *daily* with food. 39 kg or more: 300 mg (*one* capsules daily) by mouth *daily* with food.	Orthographic differences stem from the upstroke and cross stroke provided by the "t' in Reyataz. Also Reyataz contains seven letters providing additional length. Phonetic differences stem from the fact the names begin with different sounding consonants (R vs. B) and Reyataz contains three syllables with the third syllable beginning with a 't' sound not found in Beyaz. Strength: Reyataz is available in multiple strengths. None of which overlap with any of the active ingredient strengths in Beyaz.

Appendix G: Risk of medication errors due to product confusion minimized by dissimilarity of the names or distinguishing product characteristics.

Proposed name: **Beyaz** **(Drospirenone, Ethinyl Estradiol, and Levomefolate Calcium)**	**Strength:** **3 mg/0.02 mg/ 0.451 mg tablets** **(Strength may be omitted during prescribing and procurement steps of medication use process for single strength products.)**	**Usual dose:** **One tablet daily.** **(Dispense quantity likely to be written in number of packs or months for oral contraceptives**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Prevention of Failure Mode; (name confusion)**
Boniva (Ibandronate Sodium) 2.5 mg and 150 mg tablets and 3 mg/3 mL prefilled syringe. One tablet (2.5 mg) by mouth daily. One tablet (150 mg) by month once a month One syringe (3 mg) intravenously every three months. (noted on www.Boniva.com 2.5 mg tablets have not been available since June 2009)	Orthographic similarity: Both names begin with 'B" and both names have a similar number of letters (six vs. five) and length. Both products are available in oral tablets available in monthly card configuration. (Boniva 150 mg) Both products may be taken daily (Boniva 2.5 mg)	Orthographic differences minimize the potential for medication errors in the usual practice setting. Rationale: Orthographic differences stem from the fact that Boniva contains no letters providing down strokes, while Beyaz has one down stroke provided by the 'y' and may have an additional down stroke depending on how the 'z' is scripted. Although both products are prescribed for women, Boniva is for post-menopausal women for osteoporosis while Beyaz is for women of child-bearing age.

(b) (4)

[redacted]

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

Buspar (Buspirone) 5 mg, 7.5 mg (as generic), 10 mg, 15 mg and 30 mg tablets One tablet (5 - 30 mg) by mouth twice daily.	Orthographic similarity: Both names begin with a 'B'; both names contain a letter providing a down stroke in the center of the name (p vs. y) both names have a similar number of letters (six vs. five) and length. Both products are oral tablets. Similar numeric strengths appear in both products (**30 mg** vs. **3 mg**/0.02/0.451 mg).	The use of the medications in the usual practice settings minimizes the potential for medication errors. Rationale: Beyaz is an oral contraceptive with multiple active ingredients which is likely to be omitted altogether when prescribed. The numeric overlap of the strength occurs with one specific component of Beyaz (drospirenone). Thus, the potential confusion from the strength is unlikely to occur. When written or spoken in a prescription, Buspar requires a strength as part of the prescription to be complete and fillable. In addition, Buspar's frequency of use twice daily differs from daily frequency of use for Beyaz.
Repan (Acetaminophen, Butalbital and Caffeine) 325 mg/50 mg/40 mg tablets Usual dose: One or two tablets by mouth four times daily (for headache)	Orthographic similarity: Both names have the same number of letters (five) and the same shape including upstroke and down stroke in the same position (if z is scripted without a down stroke). Both products are a single strength oral tablet. Both may be written with "as directed" instructions for use.	The use of the medications in the usual practice setting minimizes the potential for medication error. Rationale: Repan is a branded generic product which carries a minimal market share as identified in preliminary drug use data.
Requip (Ropinerole) 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg and 5 mg tablets One or two tablets (0.25 mg to 8 mg) by mouth three times daily. Requip XL 2 mg, 4 mg, 6 mg, 8 mg, and 12 mg extended-release tablets One or two tablets (2 mg	Orthographic similarity: Both names begin with a similar appearing letter grouping (Requ- vs. Beya-) and both names end with a letter that can provide a down stroke when scripted (p vs. z). Both are oral solid dosage forms (tablet or extended release tablet) Similar numeric strengths appear in both products (2 mg and	The use of the medications in the usual practice settings minimizes the potential for medication errors. Rationale: While Requip and Beyaz have numerically similar strengths, Beyaz is a oral contraceptive with multiple active ingredients. The numeric overlap occurs with specific components of Beyaz (drospirenone and ethinyl estradiol). Beyaz is an oral contraceptive available in one strength which is likely to be omitted altogether when prescribed. Requip requires a strength as part of a prescription to be complete and fillable. The similar frequency of use (i.e. daily) involves only the extended release formulation (Requip XL). As Requip is available in two dosage forms with overlapping strengths,

to 24 mg) by mouth daily	3 mg vs. 3 mg/ 0.02 mg) Same frequency of administration (daily).	prescribers are likely to include the modifier, which provides orthographic difference when compared to Beyaz which includes no such modifier.
Yaz (Drospirenone and Ethinyl Estradiol) 3 mg/0.02 mg tablets One tablet daily	Orthographic and phonetic similarity: Both names contain "yaz." Both products are oral contraceptive products taken once daily packaged in 28 day cards.	Orthographic and phonetic differences minimize the potential for medication error in the usual practice setting. Rationale: Orthographic difference stem from the 'Be' in front of '-yaz' providing a different looking beginning letter, two additional letters and added length to the name when compared to Yaz. Phonetic difference also stems from the added 'Be-' as the first syllable in the name as well as providing a total of two syllables in the name.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22532	ORIG-1	BAYER HEALTHCARE PHARMACEUTICALS INC	YAZ Folate

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