CENTER FOR DRUG EVALUATION AND RESEARCH

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PROPRIETARY NAME REVIEW(S)

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Office of Medication Error Prevention and Risk Management

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Through:	Melina Griffis RPh, Team Leader Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Lubna Merchant MS, Pharm.D, Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s):	Suprenza (Phentermine HCl) Orally Disintegrating Tablets, 15 mg, 30 mg, and 37.5 mg
Applicant:	Citius Pharmaceuticals
OSE RCM #:	2011-1013

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

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EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of Suprenza as the proposed proprietary name for Phentermine Orally Disintegrating Tablets. 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 Suprenza acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA. DMEPA will notify the Applicant of these findings via letter

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 responds to a request from Citius Pharmaceuticals dated May 9, 2011 for a promotional and safety assessment of the proposed proprietary name, Suprenza.

1.2 PRODUCT INFORMATION

Suprenza (Phentermine) is indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity. The usual recommended dose of Suprenza is one tablet taken by mouth once daily (b) (4) Suprenza will be available in three strength 15 mg, 30 mg and 37.5 mg tablets, packaged in bottles containing 30 (b) (4) tablets.

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 and 2.2 identify specific information associated with the methodology for the proposed proprietary name, Suprenza. Section 2.3 identifies specific information associated with the methodology for assessment of the proposed labels and labeling.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'S' 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]

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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.

To identify drug names that may look similar to Suprenza, the DMEPA safety evaluators also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (eight letters), upstrokes (one, capital letter 'S'), down strokes (two, lower case 'p' and lower case 'z'), cross strokes (none), and dotted letters (none). Additionally, several letters in Suprenza 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 Suprenza.

When searching to identify potential names that may sound similar to Suprenza, the DMEPA staff search for names with similar number of syllables (three), stresses (Sup-ren-za), and placement of vowel and consonant sounds. (See Appendix B). The Applicant's intended pronunciation (sue pren' za) 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. (See Appendix C for samples and results).

3 RESULTS

The following sections describe the findings from our database searches, expert panel discussion, prescription analysis studies and safety evaluator risk assessment.

3.1 DATA BASE AND INFORMATION SOURCES

The DMEPA safety evaluator searches yielded a total of 30 names as having some similarity to the name Suprenza.

Twenty eight of the names were thought to look like Suprenza. These include: Suprax, Suphera, Saphris, Supatrz, Rapamune, Lupicare, Supreme, Suprofen, Sporanox, (b) (4) Supprelin LA, Suprep Bowel prep, Gilenya, Gynogen, Albenza, Scytera, Syprine, Suprevent, Synovir, Augmentin, Avinza, Relenza, Spirono, Sufaxin, Zyprexa, Zolinza, Survanta, and Symbyax. One name was thought to look and sound similar to Suprenza: Suprane. One name was thought to sound like Suprenza: Sufenta.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of March 25, 2011.

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 Suprenza.

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 41 practitioners responded to the prescription analyses studies. In the written prescription study, 31 of the participants interpreted the scripted name sample correctly in both samples. In the verbal studies, three of the participants misinterpreted the name incorrectly. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 SAFETY EVALUATOR SEARCHES

Independent searches by the primary Safety Evaluator identified five additional names which were thought to look or sound similar to Suprenza and represent a potential source of drug name confusion. These names include: (b) (4) Zuplenz, Loprox, Lupron, and Lopressor.

Thus, we evaluated a total of 35 names: 5 identified by the safety evaluator and 30 identified in section 3.1 above.

3.5 COMMENTS FROM THE DIVISION OF METABOLISM AND ENDOCRINOLOGY PRODUCTS (DMEP)

3.5.1 Initial Phase of Review

In response to the OSE, March 24, 2011 e-mail, DMEP did not object to the name, however had concerns regarding Suprenza implying "super" or "superior." These concerns were forwarded to DDMAC, who re-evaluated the proposed trade name Suprenza and did not object to it.

3.5.2 Midpoint of Review

DMEPA notified the DMEP via e-mail that we had no concerns with the proposed proprietary name, Suprenza, on April 15, 2011. Per e-mail correspondence from the DMEP on April 19, 2011, they indicated the Division had no other issues with the proposed proprietary name, Suprenza and had no additional comments.

4 DISCUSSION

This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered their comments accordingly.

(b) (4)

We also evaluated the risk of the proprietary name not including a modifier in the name that reflects that the product is ODT. However since there are no other oral dosage forms in the market with the proprietary name Suprenza, this proposed ODT product would not require a modifier to distinguish that it is an ODT dosage form. In addition, there are other approved ODT products that do not include a modifier in their proprietary name. Hence, we find this product does not require a modifier in the proprietary name.

4.1 PROMOTIONAL ASSESSMENT

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

4.2 SAFETY ASSESSMENT

DMEPA evaluated 35 names for their potential similarity to the proposed name, Suprenza. We did not identify any other aspects of the name that would be considered as a potential source for error.

Thirteen of the 35 potentially similar names did not undergo failure mode and effect analysis (FMEA) for the following reasons: Names lacking significant orthographic similarity, names with limited information, supplement not identified as drug and not dispensed pursuant to a prescription, discontinued products with no available generics, orphan drugs, proposed proprietary names withdrawn by the Applicant (see Appendices D-J).

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 22 names and lead to medication errors. This analysis determined that the name similarity between Suprenza and all of the identified names was unlikely to result in medication error for the reasons presented in Appendices K and L.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Suprenza, is not vulnerable to name confusion that could lead to medication errors, nor is it considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Suprenza, for this product at this time.

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. The Applicant will be notified of this determination via letter from DMEPA.

5.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days before approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics 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.

6 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 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

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

[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.

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 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

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

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.

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), <u>and</u> 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, Suprenza	Scripted may appear as	Spoken may be interpreted as
Upper case 'S'	F, l, j, t, a	
Lower case 'u'	Any vowel	Any vowel
Lower case 'p'	Q, y	b
Lower case 'r'	N,s,i	
Lower case 'e'	Any vowel	Any vowel
Lower case 'n'	M, r, s	m
Lower case 'z'	G,j	s
Lower case 'a'	Any vowel	Any vowel

Appendix C: **FDA Prescription Study for Suprenza**

Figure 1. Suprenza Study Samples (conducted on March 31 , 2011)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order Suprenza 30mg once daily	Suprenza 15 mg tablet po daily #30
Outpatient Rx Suprenza 15mg 1 po Qdaily #30	

Table 1: Responses to Prescription Study

INPATIENT	VOICE	OUTPATIENT
Suprenza	Ciprenza	Suprenea
Suprenza	Suprensa	Suprenza
Suprenza	Suprenza	Suprenza
Suprenza	Suprenza	Suprenza
Suprenza	Suprenza	Suprenza
Suprenza	Suprenza	Suprenza
Suprenza	Suprenza	Suprenza
Suprenza	Suprexa	Suprenza
Suprenza	suprenza	Suprenza
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Suprenza		Suprenza
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Suprenza		suprenza
Suprenza		suprenza
Suprenza		
Suprenza		
Suprenza		
suprenza		

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

Proprietary Name	Similarity to Suprenza	Proprietary Name	Similarity to Suprenza
Albenza	Look	Avinza	Look
Augmentin	Look		

Appendix E: Names with limited information.

Proprietary Name	Similarity to Suprenza	Status
Suphera	Look	Name found in POCA database. The name could not be retrieved from any pharmaceutical databases. Preliminary usage data indicates that this name is not used in prescribing.
Sufaxin	Look	Name found in Clinical Pharmacology database. The name could not be retrieved from any pharmaceutical databases. Preliminary usage data indicates that this name is not used in prescribing.
Gynogen	Look	Name found in Facts and Comparison database. The name could not be retrieved from any pharmaceutical databases. Preliminary usage data indicates that this name is not used in prescribing.

Appendix F: Supplement or product not identified as drug and not dispensed pursuant to a prescription.

Proprietary Name	Similarity to Suprenza	Reason
Supreme	Look	Blood glucose test strips
Lupicare	Look	Antidandruff shampoo

Appendix G: Orphan Drugs

Proprietary Name	Similarity to Suprenza	Reason
Suprevent	Look	This product is an Orphan drug. No commercial or pending IND or NDA was found for this product.
Synovir	Look	This product is an Orphan drug. No commercial or pending IND or NDA was found for this product.

Appendix H: Discontinued products with no available generics

Proprietary Name	Similarity to Suprenza	Reason
Suprofen	Look	Discontinued products with no available generics

Appendix I: Discontinued proprietary names for which the established name are used in usual practice settings.

Proprietary Name	Similarity to Suprenza	Status
Spirono (Spironolactone) Tablets	Look	Name discontinued, marketed under established name. Usage data indicates that the product in not prescribed under the name Spirone.

Appendix J: Proposed proprietary names

Proprietary Name	Similarity to Suprenza	Status
(b) (4)	Look	(b) (4)

Appendix K : Products with orthographic, phonetic and/or multiple differentiating product characteristics minimize the risk for medication errors

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Suprane (Desflurane) Solution for Inhalation	Look alike	Single strength 100 %	Surgical levels of anesthesia are achieved with concentrations between 2.5% to 8.5%.	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Dose: *One tablet or 15 mg, 30 mg or 37.5 mg vs. 2.5% to 8.5%* Route of Administration: *Oral vs. inhalation* Dosage form: *Tablets vs. solution for inhalation* Frequency: *Once daily vs. once during surgery*
Zuplenz (Ondansetron) Tablets	Look alike	4 mg 8 mg	4 mg to 24 mg once prior to chemotherapy or as needed for nausea and vomiting	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Zuplenz has an additional upstroke 'l' in the name which is absent in Suprenza.* Strength: *15 mg, 30 mg, and 37.5 mg vs. 4 mg and 8 mg* Frequency: *Once daily vs. once or as needed for nausea and vomiting*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Lupron (Leuprolide) Injection Solution	Look alike	5 mg/mL	Adults: 1 mg/day given subcutaneously daily. Pediatrics : 50 mcg/kg/day given subcutaneously daily.	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Suprenza (8 letters) appears longer than Lupron (6 letters) when scripted.* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. 1 mg or 50 mcg/kg/day* <u>Route of Administration:</u> *Oral vs. subcutaneously* <u>Dosage form:</u> *Tablets vs. injection solution*
Loprox (Ciclopirox) Topical gel and Shampoo	Look Alike	Gel: 0.77 % Shampoo: 1 %	Gel: one application to affected area twice daily Shampoo: one application twice weekly	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Suprenza (8 letters) appears longer than Loprox (6 letters) when scripted.* <u>Frequency:</u> *Once daily vs. twice daily or twice weekly* <u>Route of Administration:</u> *Oral vs. topical* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. one application* <u>Dosage form:</u> *Tablets vs. topical gel and shampoo*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Saphris (Asenapine) Sublingual Tablets	Look alike	5 mg 10 mg	One tablet given sublingually twice daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Saphris has an additional upstroke 'h' in the name which is absent in Suprenza.* <u>Strength:</u> *15 mg, 30 mg, and 37.5 mg vs. 5 mg and 10 mg* <u>Frequency:</u> *Once daily vs. two times daily*
Supartz (Hyaluronate and Derivatives) Injection Solution	Look alike	10 mg/mL	Inject 25 mg (2.5 mL) intra-articularly once weekly for 5 weeks	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Supartz has an additional upstroke 't' in the name which is absent in Suprenza* <u>Frequency:</u> *Once daily vs. once weekly* <u>Route of Administration:</u> *Oral vs. intra-articularly* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. 25 mg* <u>Dosage form:</u> *Tablets vs. injection solution*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Supprelin LA (Histrelin) Implant	Look alike	50 mg	50 mg implant surgically inserted subcutaneously every 12 months	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Supprelin has a additional downstroke 'p' and upstroke 'l' in the name which is absent in Suprenza* Frequency: *Once daily vs. once every 12 months* Route of Administration: *Oral vs. subcutaneously* Dose: *One tablet or 15 mg, 30 mg or 37.5 mg vs. 50 mg* Dosage form: *Tablets vs. implant*
Gilenya (Fingolimod) Capsules	Look alike	0.5 mg	One capsule taken orally once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. Orthographic: *Gilenya has a additional upstroke 'l' in the name which is absent in Suprenza* Strength: *15 mg, 30 mg, and 37.5 mg vs. 0.5 mg*
Suprep Bowel Prep Kit (Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate) Oral Solution	Look alike	17.5 gm-3.13 gm-1.6 gm per 180 mL	Take entire bottle once prior to colonoscopy	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. Frequency: *Once daily vs. once prior to colonoscopy* Dose: *One tablet or 15 mg, 30 mg or 37.5 mg vs. 180 mL* Dosage form: *Tablets vs. oral solution*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Scytera (Coal tar) Topical Foam	Look alike	2 %	one application applied once daily to four times daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Scytera has an additional upstroke 't' in the name which is absent in Suprenza* <u>Route of Administration:</u> *Oral vs. topical* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. one application* <u>Dosage form:</u> *Tablets vs. topical foam*
Syprine (Trientine) Capsules	Look alike	250 mg	500-1250 mg/day in divided doses two to four times/day	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Syprine has a additional downstroke 'y' in the name which is absent in Suprenza* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. 500 mg to 1250 mg per day* <u>Frequency:</u> *Once daily vs. two to four times daily*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Relenza (Zanamivir) Powder for Inhalation	Look alike	5 mg/blister	Two inhalations (10 mg) once daily to two times daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Relenza has an additional upstroke 'l' in the name which is absent in Suprenza* *Suprenza as a downstroke 'p' in the name which is absent in Relenza* <u>Route of Administration:</u> *Oral vs. inhalation* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. two inhalations or 10 mg* <u>Dosage form:</u> *Tablets vs. powder for inhalation*
Zolinza (Vorinostat) Capsules	Look alike	100 mg	400 mg once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Zolinza has an additional upstroke 'l' in the name which is absent in Suprenza* *Suprenza as a downstroke 'p' in the name which is absent in Zolinza* <u>Strength:</u> *15 mg, 30 mg or 37.5 mg vs. 100 mg*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Survanta (Beractant) Intratracheal Suspension	Look alike	25 mg/mL	Administer 100 mg may repeat if needed, no more frequently than every 6 hours to a maximum of 4 doses	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Survanta has an additional upstroke 't' in the name which is absent in Suprenza* *Suprenza as a downstroke 'p' in the name which is absent in Survanta.* <u>Frequency:</u> *Once daily vs. once or every 6 hours x 4 doses* <u>Route of Administration:</u> *Oral vs. Intratracheal* <u>Dose:</u> *One tablet or 15 mg, 30 mg or 37.5 mg vs. 100 mg* <u>Dosage form:</u> *Tablets vs. intratracheal suspension*
Symbyax (Olanzapien and Fluoxetine) Capsules	Look alike	3 mg/25 mg 6 mg/25 mg 6 mg/50 mg 12 mg/25 mg 12 mg/50 mg	One capsule given once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Survanta has an additional upstroke 't' in the name which is absent in Suprenza* *Suprenza as a downstroke 'p' in the name which is absent in Survanta.* <u>Strength:</u> *15 mg, 30 mg, and 37.5 mg vs. 3 mg/25 mg, 6 mg/25 mg, 6 mg/50 mg, 12 mg/25 mg, and 12 mg/50 mg*

Product name with potential for confusion	Similarity to Suprenza	Strength	Usual Dosage and Administration	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described.
Suprenza (Phentermine HCl) Orally Dintegrating Tablet	**N/A**	**15 mg 30 mg 37.5 mg**	**One tablet once daily**	**N/A**
Sufenta (Sufentanil) Injection Solution	Look and sound alike	50 mcg/mL	Adults: 5 mcg-20 mcg as needed Pediatrics: 10-25 mcg/kg (10-15 mcg/kg most common dose) maintenance: up to 1-2 mcg/kg total dose	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. <u>Orthographic:</u> *Sufenta has an additional upstroke 't' in the name which is absent in Suprenza* <u>Frequency:</u> *Once daily vs. once or as needed* <u>Route of Administration:</u> *Oral vs. Intravenous* <u>Dosage form:</u> *Tablets vs. injection solution*

Appendix L: Risk of medication errors due to product confusion minimized by dissimilarity of the names or specified product characteristics

Proposed name: **Suprenza** **(Phentermine)** **Orally Disintegrating Tablets**	**Strength:** **15 mg** **30 mg** **37.5 mg**	**Usual Dose:** **One tablet once daily**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Suprax (Cefixime) Tablets and Powder for Oral Suspension Strength/Dosage form: Tablets: 400 mg Powder for Oral Suspension: 100 mg/5 mL Dose: Adults : 400 mg every 12-24 hrs. Pediatrics: 8 mg/kg/day divided every 12-24 hrs.	**Orthographic Similarities:** Both names start with the same prefixes 'Supr' and have similar shape **Overlap in Dose:** Both products can be ordered as 1 tablet **Overlap in Route:** Both products are taken orally **Overlap in Frequency:** Both products are dosed once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** Suprenza (8 letters) and appears longer than Suprax (6 letters) when scripted An order for Suprenza will require a strength as it is available in multiple strengths vs. Suprax, which is available in single strength. There is no numerical overlap in strengths between the two.
Lopressor (Metoprolol) Tablets and Injection Solution Strength: Tablets : 50 mg 100 mg Injection: 1 mg/mL Dose: Oral : 50 mg-200 mg twice daily Intravenous: 1.25 mg -5 mg every 6-12 hours or as needed Pediatrics: 1-2 mg/kg/day; maximum 6 mg/kg/day	**Orthographic Similarities:** Both names start with the similar prefixes 'Supr' vs. 'Lopr' and have similar size and shape **Overlap in Dose:** Both products can be ordered as 1 tablet **Overlap in Route:** Both products can be given orally	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. **Rationale:** An order for Suprenza and Lopressor will require a strength as both products are available in multiple strengths. There is no numerical overlap in strengths between the two. Both products have different frequency of administration, Suprenza is dosed once daily vs. Lopressor is typically dosed twice daily or every 6 to 12 hours .

Proposed name: **Suprenza** **(Phentermine)** **Orally Disintegrating Tablets**	**Strength:** **15 mg** **30 mg** **37.5 mg**	**Usual Dose:** **One tablet once daily**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
Rapamune (Sirolimus) Tablets and Oral Solution <u>Strength:</u> Tablets : 0.5 mg 1 mg 2 mg Oral Solution : 1 mg/mL <u>Dose:</u> 1 mg to 40 mg once daily adjusted to maintain trough concentrations within desired range	**Orthographic Similarities:** Both names start with the similar prefixes 'Sup' vs. 'Rap' and have similar size and shape **Overlap in Dose:** Both products can be ordered as 1 tablet and can have a numerical overlap in dose **Overlap in Route:** Both products can be given orally **Overlap in Frequency:** Both products are dosed once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** The two names are orthographically different when scripted. An order for Suprenza and Rapamune will require a strength as both products are available in multiple strengths. There is no numerical overlap in strengths between the two.
Sporanox (Itraconazole) Capsule and Oral Solution <u>Strength:</u> Capsule:100 mg Oral Solution: 10 mg/mL <u>Dose:</u> 200 mg to 400 mg given one to three times daily	**Orthographic Similarities:** Both names start with the similar prefixes 'Sup' vs. 'Spo' and have similar size and shape **Overlap in Dose:** Both products share a numerical overlap in dose (30 mg vs. 300 mg) **Overlap in Route:** Both products can be given orally **Overlap in Frequency:** Both products are dosed once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** The two names are orthographically different when scripted. An order for Suprenza will require a strength as it is available in multiple strengths. There is no numerical overlap in strengths between the two.

Proposed name: **Suprenza** **(Phentermine)** **Orally Disintegrating Tablets**	**Strength:** **15 mg** **30 mg** **37.5 mg**	**Usual Dose:** **One tablet once daily**
Failure Mode: Name confusion	**Causes**	**Prevention of Failure (name confusion) Leading to a Medication Error**
(b) (4)		
Zyprexa (Olanzapine) <u>Strength:</u> Tablets : 2.5 mg 5 mg 7.5 mg 10 mg 20 mg Powder for Injection: 10 mg <u>Dose:</u> Oral: 5 mg to 20 mg daily Intramuscular :150 mg or 300 mg/2 weeks or 405 mg/4 weeks	**Orthographic Similarities:** Both have similar size and shape **Overlap in Dose:** Both products have an overlap in dose (15 mg) **Overlap in Route:** Both products can be given orally **Overlap in Frequency:** Both products are dosed once daily	Orthographic differences in the names, in conjunction with differences in product characteristics, minimize the likelihood of medication error in the usual practice setting. **Rationale:** The prefix 'Zyp' contains a downstroke 'y' and appears different from the prefix "Sup" when scripted. An order for Suprenza and Zyprexa will require a strength as both products are available in multiple strengths. There is no numerical overlap in strengths between the two.

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/s/

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