CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	October 25, 2012
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Drug Names and Strengths:	Lupaneta Pack (Leuprolide Acetate for Depot Suspension and Norethindrone Acetate Tablets) 3.75 mg/5 mg, 11.25 mg/5 mg
Application Type/Number:	NDA 203696
Applicant/Sponsor:	Abbott Laboratories
OSE RCM #:	2012-2334

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CONTENTS

1 INTRODUCTION

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

1.1 BACKGROUND AND REGULATORY HISTORY

The proposed proprietary name product, Lupaneta Pack (Leuprolide Acetate for Depot Injection and Norethindrone Acetate Tablets) is the subject of a 505 (b)(1) application, NDA 203696 submitted to the FDA on February 15, 2012. The name, Lupaneta Pack, is the third proposed proprietary name for this product submitted by the Applicant on October 2, 2012. This submission also includes the results of a labeling comprehension study conducted by (b) (4) and a Qualitative Integrated Summary Report.

Prior to their formal submission of a proposed proprietary name request for review, DMEPA advised Abbott Laboratories that two proposed proprietary names that they were considering, (b) (4) may be problematic. (b) (4), which appeared on all labels and labeling submitted as part of the February 15, 2012 submission, contained the USAN stem (b) (4) Additionally, both names contained part of only one of the two ingredients contained in the product; (b) (4). The proposed co-packaged product contains Lupron Depot and Norethindrone. Therefore, the naming strategy was not in accordance with 21 CFR 201.6 (b).

The Applicant submitted the proposed proprietary name, (b) (4) on April 10, 2012 for review. However, DMEPA's preliminary assessment of this name identified safety concerns due to the presence of the (b) (4), in the name because we were concerned that the modifier could be misinterpreted as other words or omitted from prescription orders. This concern was communicated to the Applicant during an April 16, 2012 teleconference and the firm subsequently withdrew the name from consideration on May 22, 2012.

On July 10, 2012 the Applicant submitted the proposed proprietary name, (b) (4) On October 2, 2012 the Applicant requested to withdraw the name, (b) (4) and submitted a new request for review of the proposed proprietary name, Lupaneta Pack (b) (4) In an email communication dated October 18, 2012, DMEPA requested the Applicant to submit their reason for withdrawing the proposed proprietary name, (b) (4). In an email correspondence dated, October 19, 2012, the Applicant stated the following:

Abbott chose to withdraw the request for the (b) (4) name based on prior identified trademark rights. However, the specific legal opinion is privileged and confidential and can't be disclosed.

1.2 REGULATORY HISTORY OF PRODUCT COMPONENTS

This Application provides for two proposed co-packaged kits each combining Lupron Depot suspension and Norethindrone Acetate Tablets. Lupron Depot suspension and Norethindrone are approved products, in the market.

One-month co-packaged kit contains:

- Lupron Depot 3.57 mg for 1-month administration kit (one prefilled dual-chamber syringe, one plunger, and two alcohol swabs) (Abbott NDA 020011) and
- Norethindrone Acetate 5 mg; 30 tablets/bottle (Glenmark ANDA 091090)

Three-month co-packaged kit that contains:

- Lupron Depot 11.25 mg for 3-month administration kit (one prefilled dual-chamber syringe, one plunger, and two alcohol swabs) (Abbott NDA 020708) and
- Norethindrone 5 mg; 90 tablets/bottle (Glenmark ANDA 091090)

Both Lupron Depot 3.75 mg for 1-month administration (sNDA 020011/S-021) and Lupron Depot 11.25 mg for 3-month administration (sNDA 020708/S011) were approved by the FDA on September 21, 2001 for the use in endometriosis patients with add-back therapy (Norethindrone 5 mg).

Norethindrone alone is approved for the treatment of secondary amenorrhea, endometriosis, and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer (Glenmark ANDA 091090: Norethindrone Acetate 5 mg Tablets; 30 tablets/bottle and 90 tablets/bottle; Office of Generic Drugs approval letter dated January 17, 2012.[1]

Additionally, the Applicant submitted container labels, carton, and insert labeling on February 15, 2012 which will be reviewed under a separate cover in OSE Review #2012-904.

1.3 PRODUCT INFORMATION

The following product information is provided in the October 2, 2012, proprietary name submission.

- Active Ingredients: Leuprolide Acetate and Norethindrone Acetate
- Indication of Use: Initial management of the painful symptoms of endometriosis and management of recurrence of symptoms.
- Route of Administration: Intramuscular and oral
- Dosage Form: Injection and Tablets
- Strength: 3.75 mg and 5 mg and 11.25 mg and 5 mg
- Dose and Frequency:
    - Lupron Depot 3.75 mg for 1-month administration given as a single intramuscular injection every 1 month, and Norethindrone Acetate 5 mg Tablets taken orally once per day for one month.

[1] Orleans, R.J and Soule, L.M. Clinical Filing Checklist For a New NDA/BLA. April 12, 2012

- Lupron Depot 11.25 mg for 3-month administration given as a single intramuscular injection once every 3 months, and Norethindrone 5 mg tablets taken orally once per day for 3 months.

- How Supplied:

  Lupaneta Pack for 1-month co-packaged kit is available in cartons containing:

  - Lupron Depot 3.75 mg for 1-month administration Kit (one prefilled dual-chamber syringe, one plunger, and two alcohol swabs
  - Norethindrone Acetate 5 mg 30 count bottle

  Lupaneta Pack for 3-month co-packaged kit is available in cartons containing:

  - Lupron 11.25 mg for 3-month administration Kit (one prefilled dual-chamber syringe, one plunger, and two alcohol swabs
  - Norethindrone Acetate 5 mg 90 count bottle

- Storage: 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)

- Container and Closure System: The proposed co-packaged kit is an outer carton container (non-functional secondary packaging material) that will contain the already marketed Lupron Depot syringe Kit and Norethindrone bottle components within the carton, which is secured with an adhesive tamper-evident seal.

  Lupron Depot prefilled dual chamber syringe consists of:

  - Gray (b) (4) rubber stopper
  - Colorless (b) (4) glass cartridge (b) (4) (b) (4) (USP Type I glass)
  - Front assembly that consists of a 23 G x 2.5 inch needle, a sheath, and luer lock hub. (b) (4)
  - Finger grip made of colored (b) (4)
  - Plunger rod made of colored (b) (4)

  Norethindrone (30 and 90 count bottles):

  50 cc white opaque, high density polyethylene bottle with (b) (4) closure with heat seal liner, 2 gram sorb-it canister, purified cotton, container label, and literature.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive

and Urologic Products concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The October 2, 2012 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Lupaneta Pack, consists of "Lup", derived from the brand name "Lupron" which is one component in the co-packaged kit, and "neta", derived from "Norethindrone Acetate" which is the other component in the co-packaged kit. The "Pack" modifier identifies the product as combination therapy.

The root name, Lupaneta, is comprised of the prefix "Lup" for Lupron and the suffix "neta" to represent norethidrone acetate. The letter string "neta" is a medical abbreviation for norethidrone acetate.[2] Normally DMEPA discourages the use of medical abbreviations in a proprietary name because this can inadvertently be a source of error. However, this letter string is embedded in the proprietary name and based on our FMEA, we do not envision that it will result in a medication error because the letter string does not appear similar to a route of administration, frequency, strength, dose, or any other medical terms that would result in error when combined with the letter string "Lupa". Additionally, review of ISMP's Error-Prone Abbreviation List does not identify 'NETA' as an error-prone abbreviation.[3] Therefore, in this circumstance we find the inclusion of this letter string acceptable.

The Applicant submitted qualitative information supporting the use of this root name. The studies included patients, prescribers, and nurse, but did not contain pharmacist. The studies did not specifically ask participants what the prefix and suffix represent, but did ask participants if the names are appropriate given the active ingredients. Lupaneta performed average across several measures including performance of likability, appropriateness, uniqueness, memorability, and ability to say, read, and write. Lupaneta was given a moderate vulnerability score of 3 by (b) (4) due to orthographic similarity to Lunesta. The name Lunesta is evaluated in this review.

Even though the Applicant only provided qualitative data to support the use of "Lupaneta" we find that this root name does not violate 21CFR 201.6(b) (i.e. "*The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though*

[2] MediLexicon International Ltd. Bexhill-on-Sea, UK. 2004-2012.

[3] Institute for Safe Medication Practices. ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations. Available at http://www.ismp.org/Tools/errorproneabbreviations.pdf

the names of all such ingredients are stated elsewhere in the labeling.") because the root name "Lupaneta" does not represent a single ingredient of a multi-ingredient product.

Although the inclusion of modifiers in proprietary names can be problematic because a modifier may be omitted or misinterpreted for other words, DMEPA finds the use of the modifier "Pack" for this co-packaged product appropriate because this is a combination product that consists of two components. The modifier "Pack" is also used for a similar co-packaged product containing an injection and an oral dosage form that was evaluated by DMEPA and approved by the FDA (i.e. Pegintron/Rebetol Combo Pack, BLA 125196, approved on June 13, 2008). While the inclusion of the modifier "Pack" may be helpful in identifying the proposed product as a combination product, omission of the modifier "Pack" is a probability and may present a concern. Therefore, in our assessment of the proposed proprietary name, Lupaneta Pack, we analyzed the name with the modifier "Pack" (i.e. Lupaneta Pack) and without the modifier "Pack" (i.e. 'Lupaneta') to ensure there are no orthographic and /or phonetic similarities between the root name and other marketed products or those pending approval.

Furthermore, the naming strategy of not including the entire name "Lupron" in the proposed proprietary name can help minimize the risk of medication errors that could occur by using the entire name 'Lupron' plus a modifier in the event of the omission of that modifier or abbreviating the name. Please refer to Section 3 Discussion for further details.

2.2.3 FDA Name Simulation Studies

Thirty-two practitioners participated in DMEPA's prescription studies. However, one participant from the outpatient studies stated that he could not read the prescription and another participant stated that she did not provide a sample because she is with the Lupaneta Pack team in DRUP and has previous knowledge of the proposed proprietary name, Lupaneta Pack. Therefore thirty responses were evaluated. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Seven of the thirty participants interpreted the name correctly as Lupaneta Pack. Eight voice prescription study participants misinterpreted the fourth position letter 'a' as the letters 'e', 'u', and 'i'. Two participants from the voice prescription studies omitted the modifier 'Pack'. Twelve participants from the outpatient or inpatient prescription studies misinterpreted the beginning letter string 'Lu' as one of the following: 'Im', 'Ui', 'Ur', and 'We'. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE, October 17, 2012 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

The proposed proprietary name, Lupaneta Pack, will represent a co-packaged product containing Lupron Depot 3.75 mg for 1-month administration (or Lupron Depot 11.25 mg for 3-month administration) and Norethindrone Acetate Tablets, 5 mg,

30 count (or 90 count) bottle. We evaluated the entire name "Lupaneta Pack" for look-alike and sound-alike concerns as well as each component of the name "Lupaneta" and "Pack" separately to see if the individual parts of each name would contribute to medication errors.

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

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

Look Similar					
Name	***Source***	***Name***	***Source***	***Name***	***Source***
Lapatinib	EPD	Lutropin Alfa	EPD	(b) (4) ***	EPD
Lupron	EPD	Tradjenta	EPD	Lipidol	EPD
Tegretol	EPD	Loperamide	EPD	Luprinol	EPD
Liquiset	EPD	Lunesta	EPD	Zegerid	EPD
Supartz	EPD	Tapazole	EPD	Topicort	EPD
Lazanda	EPD	Topicale	EPD	Lupicare Dandruff	EPD
Lipofen	EPD	Lipodox	EPD	Lepirudin	EPD
Zyprexa	EPD	Tagamet	EPD	Tazicef	EPD
Tofranil	EPD	Suprenza	PR	(b) (4) **	PR
(b) (4)	PR	Xopenex	PR	Cogentin	PR
Concerta	PR	Capoten	PR	Alupent	EPD
(b) (4)	EPD	Lagesic	EPD	Zometa	EPD
Supervite	EPD	Caprelsa	EPD	[redacted]	[redacted]
Look and Sound Similar					
Lipitor	EPD	(b) (4)	EPD	(b) (4)	EPD

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Our analysis of the 41 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 41 names will not pose a risk for confusion as described in Appendix D through E.

2.2.6 Failure Mode and Effects Analysis of a Dual Name

Because this is a co-packaged product we evaluated whether using a unique root name for this product would be better than using the root name Lupron plus a modifier. Neither option is without risk. Using the root name Lupron plus a modifier is problematic because if a modifier is omitted there is a chance the wrong product (e.g. Lupron Depot only) can be dispensed. Using a unique name that is not Lupron would minimize confusion between this product and the currently marketed Lupron products because the names are different. However, there is the possibility that having a unique root name could lead to possible concomitant therapy if a person is prescribed both Lupaneta Pack and Lupron. However, having a name that contains the same first 3 letters of each name and providing the components of Lupaneta Pack on the outer carton labeling in a prominent fashion may help minimize the risk of concomitant therapy because this will help alert patients and healthcare practitioners that these products contain the same active ingredient.

Therefore, DMEPA finds this naming strategy of using a unique root name acceptable for the proposed co-packaged product.

2.2.7 Failure Mode and Effects Analysis of Modifier "Pack"

The modifier Pack has been used for another marketed product (e.g. Pegintron/Rebetol Combo Pack) and has not been a source of confusion or error. We evaluated the risk of omission of this modifier and found that even if the modifier is omitted, a medication error would not occur because the root name Lupaneta is not orthographically or phonetically similar to other names that are currently marketed. Additionally, our evaluation of the modifier "Pack" did not identify it to be a word that may contribute to medication errors because "Pack" does not contain a USAN stem, does not contain a route of administration, dosage form, dosing interval, and medical or product name abbreviations. Thus, we find the use of the modifier "Pack" for this product acceptable.

2.2.8 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on October 22, 2012. At that time we also requested additional information or concerns that could inform our review. In a meeting held on October 23, 2012, the Division of Reproductive and Urologic Products stated no additional concerns with the proposed proprietary name, Lupaneta Pack.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. The Applicant will be notified via letter of this finding with the comments in Section 4.1.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Lupaneta Pack, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your October 2, 2012 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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

4 REFERENCES

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

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

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

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

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

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

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

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

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

   USPTO provides information regarding patent and trademarks.

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

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

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

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

   The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

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

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

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

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

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

    USAN Stems List contains all the recognized USAN stems.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

APPENDICES

Appendix A

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

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [1]

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

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

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

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

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	**Considerations when Searching the Databases**		
	Potential Causes of Drug Name Similarity	*Attributes Examined to Identify Similar Drug Names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

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

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

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

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

3. FDA Prescription Simulation Studies

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

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

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

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

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

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

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

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

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

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

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

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

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

past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Lupaneta Pack	Scripted May Appear as	Spoken May Be Interpreted as
Capital Letter 'L'	'Z', 'C', 'S', 'X', 'T'	'W'
Letter string 'Lu'	'Ui', 'Ur', 'W'	
Lower case 'l'	'b', 'i', 'e', 's', 'A', 'P'	'w'
Lower case 'u'	'n', v', 'y', 'w', any vowel	Any vowel
Lower case 'p'	'x', 'yn', 'ys', 'g', 'j', 'l'	'b'
Lower case 'a'	'o', 'u', 'e'	Any vowel
Lower case 'n'	'x', 'r', 'm', 'u', 's', 'h'	'dn', 'gn', 'kn', 'mn', pn, 'm'
Lower case 'e'	'i', 'o', 'u', 'l', 'p'	Any vowel
Lower case 't'	'x', 'b', 'f', 'A', 'r'	'd'
Capital letter 'P'	'D', 'B'	'B'
Lower case 'c'	'e', 'i', 'a', 'l'	'z', 'k', 's'
Lower case 'k'	'h', 'x', 'b', 'la'	'c', 'g'

Appendix C: Prescription Simulation Samples and Results

Figure 1. Lupaneta Pack Study (Conducted on 10/19/12)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Lupaneta Pack 11.25mg/5mg for 3 months administered	Lupaneta Pack 3.75 mg As directed #1 pack
Outpatient Prescription: Lupaneta Pack 3.75mg As directed #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

32 People Responded

Study Name: Lupaneta Pack

Total	12	10	10	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CANNOT READ	0	0	1	1
IMPANETA PACK	0	0	1	1
LUPANETA PACK	3	1	2	6
LUPANETA PACK 11.25 MG/5 MG	1	0	0	1
LUPANETTA	0	1	0	1
LUPENETA	0	1	0	1
LUPENETA PACK	0	1	0	1
LUPENETTA PACK	0	1	0	1
LUPINETA PACK	0	1	0	1
LUPINETTA PAC	0	1	0	1
LUPINETTA PACK	0	2	0	2
LUPINETTA PAK	0	1	0	1
LUPUNETA PACK	1	0	0	1
LUPURETA PACK	1	0	0	1
I know it's Lupaneta, but it sure doesn't look like that here.	0	0	1	1
UIPANETA PACK	1	0	1	2
URIPANETA PACK	1	0	0	1
URPANETA PACK	2	0	4	6
WEPANETA PACK	2	0	0	2

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

No.	Proprietary Name	Active Ingredient	Similarity to Lupaneta Pack	Failure preventions
1.	Lapatinib	Established name for Tykerb	Look	The name pair has sufficient orthographic and /or phonetic differences.
2.	Lutropin Alfa	Established name for Luveris	Look	The name pair has sufficient orthographic and /or phonetic differences.
				(b) (4)
4.	Lupron	Leuprolide Acetate	Look	The name pair has sufficient orthographic and /or phonetic differences.
5.	Tradjenta	Linagliptin	Look	The name pair has sufficient orthographic and /or phonetic differences.
6.	Lipidol	Papaver somniferum L. and Papaver bracteatum. Family: Papaveraceae (Poppyseed poppy)	Look	Name identified in the Facts and Comparisons database which states that clinical trials are lacking to guide dosage.
7.	Tegretol	Carbamazepine	Look	The name pair has sufficient orthographic and /or phonetic differences.
8.	Loperamide	Established name for Imodium	Look	The name pair has sufficient orthographic and /or phonetic differences.
9.	Luprinol	Multiple indgredients	Look	Name identified in the Natural Medicines database. This is an Ephedrine containing product and is no longer marketed in the US.
10.	Liquiset	N/A	Look	Name identified in the Facts and Comparisons database, however, it could not be replicated in this or any of the available databases.

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

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

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

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
1.	Lunesta (Eszopiclone) Tablets 1 mg, 2 mg, 3 mg Usual Dose: One tablet orally immediately before bedtime.	Orthographic: Both names share the beginning letter string 'Lu-' followed by similar scripted letter strings in the same position of each name ('-an-' vs. '-es-'), and the ending letter string '-ta'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Orthographic: The downstroke 'p' in Lupaneta Pack in addition to the extra letter 'e' preceding the upstroke 't' in Lupaneta provide a different shape and a longer appearance for this name and can help differentiate Lupaneta Pack from Lunesta when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 1 mg, 2 mg, and 3 mg

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
2.	Zegerid (Omeprazole, Sodium Bicarbonate) Capsules, 20 mg, 40 mg Powder for Suspension, 20 mg 40 mg Usual Dose: 20 mg to 40 mg orally once daily.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'Z'), followed by similar scripted vowels ('u' vs. 'e'), a downstrke in the third position ('p' vs. 'g') followed by similar scripted letter strings ('-anet-' vs. '-erid'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Solid oral Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One (tablet or injection vs. capsule or packet)	Orthographic: The extra ending letter 'a' in Lupaneta provides a different shape and a longer appearance for this name and can help differentiate Lupaneta Pack and Zegerid when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 20 mg and 40 mg

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
3.	Supartz (Hyaluronate and Derivatives) Injection Solution, 10 mg/mL Usual Dose: Inject 25 mg (2.5 mL) intra-articularly once weekly for 5 weeks.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'S') followed by the letter string '-up-', similar position upstroke 't' (seventh vs. sixth position), and ending letters that may appear similar when scripted ('a' vs. 'z' if not scripted in lower case). Partial Overlap in the Route of Administration: Parenteral Partial Overlap in the Dosage Form: Injection Partial Overlap in the Frequency of Administration: Once (daily, every month, or every 3months vs. weekly)	Orthographic: The extra letter 'e' preceding the upstroke 't' in Lupaneta Pack provides a longer appearance for this name and can help differentiate Lupaneta Pack and Supartz when scripted. Strength: Multiple strengths (3.75mg/5 mg and 11.25 mg/5 mg vs. 10 mg/mL Usual Dose: 3.75 mg/5 mg or 11.25 mg/5 mg vs. 25 mg (or 2.5 mL)

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
4.	Tapazole (Methimazole) Tablets 5 mg, 10 mg Usual Dose: Adults: The initial daily dosage is 15 mg for mild hyperthyroidism, 30 to 40 mg for moderately severe hyperthyroidism, and 60 mg for severe hyperthyroidism, divided into 3 doses at 8-hour intervals. The maintenance dosage is 5 to 15 mg daily. Pediatrics: Initially, the daily dosage is 0.4 mg/kg of body weight divided into 3 doses and given at 8-hour intervals. The maintenance dosage is approximately 1/2 of the initial dose.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'T') followed by similar scripted vowels ('u' vs. 'a'), third position downstroke 'p' followed by similar scripted letter strings ('-aneta' vs. '-azole' if the letter 'z' is not scripted in lower case). Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Strength: 5 mg Partial Overlap in the Usual Dose: One tablet	Although the two products share the 5 mg strength, the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product, Lupaneta Pack (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product. A pharmacist who misinterprets a prescription written for Tapazole, as Lupaneta Pack, would be prompted to call the physician to verify the prescription and the strength which would result in the correct product being dispensed. Therefore, the risk of medication error due to confusion due to orthographic similarity between Lupaneta pack and Tapazole is minimized.

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
5.	Topicort (Desoximetasone) Cream, 0.25%, 0.05% Gel, 0.05% Ointment, 0.25% Usual Dose: Apply a thin film to the affected area(s) topically twice daily.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'T') followed by similar scripted vowels ('u' vs. 'o'), third position downstroke 'p' and upstroke 't' in similar positions of each name (seventh vs. eighth positions). Partial Overlap in the Usual Dose: One (tablet or injection vs. application) or both products may be prescribed 'as directed'.	Orthographic: The ending letter 'a' in Lupaneta Pack (vs. the ending upstroke 't' in Topicort) provides a different shape for this name and can help differentiate Lupaneta Pack and Topicort when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 0.25% and 0.05%
6.	Lazanda (Fentanyl Citrate) Spray 100 mcg per spray, 400 mcg per spray Usual Dose: A single spray (100 mcg to 800 mcg) into one nostril or a single spray into each nostril (2 sprays). Maximum of four doses in 24 hours.	Orthographic: Both names share the beginning letter 'L' followed by similar scripted vowels ('u' vs. 'a'), a third position downstroke ('p' vs. 'z' if the letter 'z' is scripted as a downstroke), and similar scripted ending letter strings ('-aneta' vs. '-anda'). Partial Overlap in the Usual Dose: One (tablet or injection vs. spray)	Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 100 mcg and 400 mcg per spray

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
7.	Topicale (Benzalkonium Chloride, benzocaine) Gel, 18% Ointment, 18% Solution, 18% Usual Dose: Apply to the affected area(s) no more than 3 to 4 times per day and for no more than 5 days.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'T') followed by similar scripted vowels ('u' vs. 'o'), a third position downstroke 'p', and similar scripted ending letter strings ('-eta' vs. '-ale'). Partial Overlap in the Usual Dose: One (tablet or injection vs. application) or both products may be prescribed 'as directed'.	Strength: Multiple strengths (3.75mg/5 mg and 11.25 mg/5 mg) vs. single strength (18%).
8.	Lupicare Dandruff (Salicylic Acid) Shampoo, 2% Lupicare Psoriasis (Salicylic Acid) Cream, 2% Usual Dose: Shampoo: massage into wet hair or affected area; leave in place for several minutes; rinse thoroughly. Use 2 to 3 times a week, or as directed by healthcare provider. Cream: use to cleanse skin one to two times daily.	Orthographic: Both names consist of 8 letters, share the beginning letter string 'Lup-', and similar scripted vowels in the sixth and eighth position of each name ('e' vs. 'a' and 'a' vs. 'e' respectively). Partial Overlap in the Usual Dose: One (tablet or injection vs. application)	Orthographic: The upstroke 't' in Lupaneta pack (vs. the letter 'r' in Lupicare) provides a different shape for this name and can help differentiate Lupaneta pack and Lupicare Dandruff (or Lupicare Psoriasis) when scripted. Strength: Multiple strengths (3.75mg/5 mg and 11.25 mg/5 mg) vs. single strength (2%)

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
9.	Lipofen (Fenofibrate) Capsules 50 mg, 150 mg Usual Dose: 50 mg to 150 mg (or one capsule) orally once daily.	Orthographic: Both names share the beginning letter 'L', the third position downstroke 'p', and similar scripted letter strings ('-ta' vs. '-fe-'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Solid oral Partial Numerical Overlap in the Strength: 5 mg may be misinterpreted as 50mg Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Orthographic: The extra letter string '-ne-' placed between the upstrokes 'L' and 't' in Lupaneta pack and the ending letter 'n' in Lipofen provide different shapes for each name and can help differentiate Lupaneta pack and Lipofen when scripted. Additionally, although the 5 mg strength of Lupaneta Pack may be confused with the 50 mg strength of Lipofen, if 5 mg is scripted with a tariling zero (i.e. 5.0), the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product, Lupaneta Pack (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product and it would prompt a phone call by the pharmacist to the physician to verify the prescription thus, eliminating the risk of medication error due to confusion.

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
10.	Lipodox (Doxorubicin Hydrochloride) Injection, 2 mg/mL Usual Dose: Breast cancer/ovarian cancer: Administer 50 mg/m2 intravenously every 4 weeks. AIDS-KS patients: Administer 20 mg/m2 intravenously over 30 minutes once every three weeks.	Orthographic: Both names share the beginning letter 'L', the third position downstroke 'p' followed by similarly scripted vowels ('a' vs. 'o'), and similar scripted letter strings in similar positions of each name ('-eta' vs. '-do'). Partial Overlap in the Route of Administration: Parenteral Partial Overlap in the Dosage Form: Injection	Orthographic: The ending cross stroke 'x' in Lipodox provides a longer appearance for the letter grouping following the upstroke 'd' in Lipodox (vs. only one letter following the upstroke 't' in Lupaneta Pack) which can help differentiate Lupaneta Pack and Lipodox when scripted. Strength: Multiple strengths (3.75 mg/5 mg and 11.25 mg/5 mg) vs. single strength (2 mg/mL).

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
11.	Lepirudin (established name for Refludan) Injection, 50 mg/vial Usual Dose: 0.4 mg/kg body weight (up to 110 kg) slowly intravenously (eg, over 15 to 20 seconds) as a bolus dose, followed by 0.15 mg/kg body weight (up to 110 kg per hour as a continuous intravenous infusion for 2 to 10 days or longer.	Orthographic: Both names share the beginning letter 'L' followed by a vowel ('u' vs. 'e'), a third position downstroke 'p', and similar scripted letter strings ('-net-' vs. '-rud-') in the same position of each name. Partial Overlap in the Route of Administration: Parenteral Partial Overlap in the Dosage Form: Injection Partial Numerical Overlap in the Strength: 5 mg may be misinterpreted as 50 mg	Orthographic: The extra ending letter 'n' in Lepirudin provides a longer appearance for this name and can help differentiate Lupaneta pack and Lepirudin when scripted. Additionally, although the 5 mg strength of Lupaneta Pack may be confused with the 50 mg strength of Lepirudin, if 5 mg is scripted with a trailing zero (i.e. 5.0), the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product, Lupaneta Pack (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product and it would prompt a phone call by the pharmacist to verify the prescription with the physician, thus, eliminating the risk of medication error due to confusion.

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
12.	Zyprexa (Olanzapine) 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: Both names share similar scripted beginning letters ('L' vs. 'Z') followed by similar scripted letters ('u' vs. 'y'), third position downstroke 'p', ending letter 'a' preceded by similar scripted cross strokes ('t' vs. 'x'). Overlap in the Route of Administration: Intramuscular and oral Overlap in the Dosage Form: Injection and tablets Partial Overlap in the Strength: 5 mg Partial Overlap in the Usual Dose: One tablet	Although the two products share the 5 mg strength, the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product, Lupaneta Pack (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product. A pharmacist who misinterprets a prescription written for Zyprexa 5 mg, as Lupaneta Pack, would be prompted to call the physician to verify the prescription and the strength which would result in the correct product being dispensed. Therefore, the risk of medication error due to confusion due to orthographic similarity between Lupaneta pack and Zyprexa is minimized.

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
13.	Tagamet (Cimetidine) Tablets 200 mg Usual Dose: Take one tablet orally daily. No more than 2 tablets in 24 hours.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'T') followed by similar scripted letter strings ('-up-' vs. '-ag-' and '-anet-' vs. '-met'). Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Orthographic: The ending letter 'a' in Lupaneta pack provides a different shape for this name and can help differentiate Lupaneta Pack from Tagamet when scripted. Strength: Multiple strengths (3.75 mg/5 mg and 11.25 mg/5 mg) vs. single strength (200 mg)

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
14.	Tazicef (Ceftazidime) Injection 1 gram, 2 gram, 6 gram Usual Dose: The usual adult dosage is 1 gram intravenously or intramuscularly every 8 to 12 hours. The dosage and route should be determined by the susceptibility of the causative organisms, the severity of infection, and the condition and renal function of the patient.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'T') followed by a vowel and a downstroke ('-up-' vs. '-az-' if the letter 'z' is scripted as a downstroke), and a sixth position letter 'e' followed by a cross stroke ('t' vs. 'f'). Partial Overlap in the Route of Administration: Intramuscular Partial Overlap in the Dosage Form: Injection	Orthographic: The ending letter 'a' in Lupaneta Pack provides a different shape and a longer length for this name and can help differentiate Lupaneta Pack from Tazicef when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 1 gram, 2 gram, and 6 grams

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
15.	Tofranil (Imipramine Hydrochloride) Tablets, 10 mg, 25 mg, 50 mg Injection, 25 mg Usual Dose: Injection: up to 100 mg/day intramuscularly in divided doses. Tablets: Hospitalized Patients: initially, 100 mg/day in divided doses gradually increased to 200 mg/day, if no response after two weeks, increase to 250 to 300 mg/day. Outpatients: initially, 75 mg/day increased to 150 mg/day. Maintenance, 50 to 150 mg/day. Adolescent and Geriatric Patients: initially, 30 to 40 mg/day.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'T') followed by similar scripted letter strings '-up-' vs. '-of-' if the letter 'f' is scripted as a downstroke), and similar scripted letter strings in similar positions of each name ('-net-' vs. '-nil'). Overlap in the Route of Administration: Intramuscular and oral Overlap in the Dosage Form: Injection and tablets Partial Numerical Overlap in the Strength: 5 mg may be misinterpreted as 50 mg Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet or injection	Orthographic: The ending letter 'a' in Lupaneta pack provides a different shape for this name and can help differentiate Lupaneta Pack and Tofranil when scripted. Additionally, although the 5 mg strength of Lupaneta Pack may be confused with the 50 mg strength of Tofranil, if 5 mg is scripted with a trailing zero (i.e. 5.0), the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product, Lupaneta Pack (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product and it would prompt a phone call by the pharmacist to verify the prescription with the physician, thus, eliminating the risk of medication error due to confusion.

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
16.	Lipitor (Atorvastatin) Tablets 10 mg, 20 mg, 40 mg, 80 mg Usual Dose: 10 mg to 80 mg (or one tablet) orally once daily.	Orthographic/Phonetic: Both names share the beginning letter 'L', letter string '-pi-' in the same position of each name, and upstroke 't' followed by similar scripted round vowels ('a' vs. 'o'). Phonetically, both names share the sound 'L' in the first syllable, and the sound 'p' in the second syllable of each name when spoken. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Orthographic/Phonetic: The extra letter string '-ne-' between downstorke 'p' and upstroke 't' in Lupaneta provides a longer appearance and a different shape for this name and can help differentiate Lupaneta Pack and Lipitor when scripted. Phonetically, the root name, Lupaneta consists of 4 syllables vs. only 3 syllables in Lipitor. Additionally, the letter string 'neta' sounds different than the letter string 'tor' and can help differentiate Lupaneta Pack and Lipitor when spoken. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 10 mg, 20 mg, 40 mg, and 80 mg

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)Dosage Form(s): Injection and tabletsStrength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
			(b) (4)

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

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**

(b) (4)

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

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
19.	Xopenex (Levalbuterol Hydrochloride) Inhalation Solution 0.31 mg, 0.63 mg, 1.25 mg Usual Dose: Children 6–11 years old: 0.31 mg three times a day, by nebulization. Adults and Adolescents 12 years and older: 0.63 mg three times a day, every 6 to 8 hours, by nebulization.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'X') followed by vowels ('u' vs. 'o'), a third position downstroke 'p' followed by similar scripted letter strings ('-anet-' vs. '-enex'). Partial Overlap in the Route of Administration: Oral Partial Overlap in the Usual Dose: One (tablet or injection vs. inhalation)	Orthographic: The extra ending letter 'a' following the cross stroke 't' in Lupaneta Pack (vs. no letters following the cross stroke 'x' in Xopenex) provides a different shape and a longer length for this name and can help differentiate Lupaneta Pack and Xopenex when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 0.31 mg, 0.63 mg, and 1.25 mg Frequency of Administration: Once daily, Once every month, or once every 3 months vs. 3 times a day.

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
20.	Cogentin (Benztropin Mesylate) Injection, 1 mg/mL Usual Dose: 1 mg to 4 mg intravenously or intramuscularly once or twice daily (dose is individualized).	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'C') followed by a vowel, a third position downstroke ('p' vs. 'g'), similar scripted letter strings in similar positions of each name ('-an-' vs. '-en'), and similar position upstroke 't' (seventh vs. sixth position). Partial Overlap in the Route of Administration: Intramuscular Partial Overlap in the Dosage Form: Injection Partial Overlap in the Frequency of Administration: Once daily	Orthographic: The skinny letter 'i' following the upstroke 't' in Cogentin provides a longer length for the suffix following the upstroke 't' and can help differentiate Lupaneta pack and Cogentin when scripted. Strength: 3.75mg/5 mg and 11.25 mg/5 mg vs. 1 mg/mL

No.	**Proposed name:** **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
21.	Concerta (Methylphenidate Hydrochloride) Extended-release Tablets 18 mg, 27 mg, 36 mg, 54 mg Usual Dose: 18 mg to 54 mg (or one tablet) orally once daily.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'C') followed by similar scripted vowels ('u' vs. 'o'), and the ending letter string '-ta'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 18 mg, 27 mg, 36 mg, and 54 mg

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate) Dosage Form(s): Injection and tablets Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
22.	Capoten (Captopril) Tablets 12.5 mg, 25 mg, 50 mg, 100 mg Usual Dose: 12.5 mg to 100 mg (or one tablet) orally one to three times daily.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'C') followed by a vowel ('u' vs. 'a'), a third position downstroke 'p' followed by similar scripted round vowels ('a' vs. 'o'), and similar position upstroke 't' followed by similar scripted vowels ('a' vs. 'e'). Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Partial Overlap in the Usual Dose: One tablet	Orthographic: The letter string '-ne-' between the downstroke 'p' and the upstroke 't' in Lupaneta pack (vs. only the letter 'o' between the downstroke 'p' and the upstroke 't' in Capoten) and the ending letter 'n' in Capoten provide different shapes for each name and can help differentiate Lupaneta Pack and Capoten when scripted. Additionally, although the 5 mg strength of Lupaneta Pack may be confused with the 50 mg strength of Capoten, if 5 mg is scripted with a trailing zero (i.e. 5.0), the 5 mg is a fixed strength in the combination strength presentation of the proposed co-packaged product (i.e. 3.75 mg/5 mg and 11.25 mg/5 mg). Therefore, it is unlikely for a prescriber to write an order for Lupaneta pack 5 mg because this will not differentiate the two different strengths (or frequency of administration) of this product. and it would prompt a phone call by the pharmacist to verify the prescription with the physician, thus, eliminating the risk of errors.

No.	**Proposed name: Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s): Injection and tablets** **Strength(s): 3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**	**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
23.	Suprenza (Phentermine HCL) Orally Disintegrating Tablets 15 mg, 30 mg, 37.5 mg Usual Dose: one tablet orally once daily before breakfast or 1to 2 hours after breakfast.	Orthographic: Both names consist of 8 letters, share similar scripted beginning letters ('L' vs. 'S') followed by the letter string '-up-', and the ending letter 'a'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration: Once daily Possible Confusion in Strength 3.75 mg in Lupaneta Pack may be confused as 37.5 mg or vise versa Partial Overlap in the Usual Dose: One tablet	Orthographic: The letter string '-net-' in Lupaneta Pack does not appear similar to the letter string '-enz-' in Suprenza and can help differentiate Lupaneta Pack from Suprenza when scripted.

Proposed name: **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
24.	Caprelsa (Vandetanib) Tablets 100 mg, 300 mg Usual Dose: 300 mg (or one tablet) orally once daily. For patients with creatinine clearance of less than 50 mL/min, reduce the starting dose to 200 mg.	Orthographic: Both names consist of eight letters, share a third position downstroke 'p', the ending letter 'a', similar scripted beginning letter strings ('Lu-' vs. 'Ca-'), and similar scripted letter strings in similar positions of each name ('-net-' vs. '-rel-'. Partial Overlap in the Route of Administration: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Frequency of Administration and the Usual Dose: One tablet	Orthographic: The letter 's' following the upstroke 'l' in Caprelsa and the letter 'a' following the downstroke 'p' in Lupaneta Pack provide different lengths following the upstrokes 't' and 'l' and between the downstroke 'p' and the upstrokes 't' and 'l', respectively and can help differentiate Lupaneta Pack and Caprelsa when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 100 mg and 300 mg

Proposed name: **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
25.	Alupent (Metaproterenol Sulfate) Solution for Inhalation 0.4% and 0.6% Usual Dose: One vial every 4 hours 3 to 4 times per day for acute attacks of bronchospasm.	Orthographic: Both names share the letter string '-up-' in similar positions of each name followed by similar scripted letter strings ('-an-' vs. '-en-'), and a seventh position cross stroke 't'. Partial Overlap in the Usual Dose: One (tablet vs. vial)	Orthographic: The upstroke 'l' in the second position of Alupent and the extra ending letter 'a' in Lupaneta provide different shapes for each name and can help differentiate Lupaneta pack and Alupent when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 0.4% and 0.6%
26.	Lagesic (Acetaminophen and Phenyltoloxamine Citrate) Tablets, 600 mg/66 mg Usual Dose: One to two tablets orally every four hours (maximum of eight tablets per day).	Orthographic: Both names share the beginning letter 'L' followed by similar scripted letter strings ('-upane-' vs. '-agesi-'). Overlap in the Route of Administation: Oral Partial Overlap in the Dosage Form: Tablets Partial Overlap in the Usual Dose: One tablet	Orthographic: The upstroke 't' in Lupaneta pack provides a different shape for this name and can help differentiate Lupaneta Pack and Lagesic when scripted. Strength: Multiple strengths (3.75 mg/5 mg and 11.25 mg/5 mg) vs. single strength (600 mg/66 mg).

Proposed name: **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
27.	Zometa (Zoledronic Acid) Solution for Injection 4 mg/100 mL and 4 mg/5 mL Usual Dose: Hypercalcemia of malignancy: 4 mg as a single dose intravenous infusion over no less than 15 minutes. Multiple myeloma and metastatic bone lesions of solid tumors: for patients with creatinine clearance of greater than 60 mL/min, 4 mg infused intravenously over no less than 15 minutes every 3 to 4 weeks.	Orthographic: Both names share the ending letter string '-eta' preceded by similar scripted letters ('n' vs. 'm') and similar scripted beginning letter strings ('Lu-' vs. 'Zo-'). Partial Overlap in the Route of Administration and Dosage Form: Peripheral injection	Orthographic: The downstroke 'p' in Lupaneta provides a different shape for this name and can help differentiate Lupaneta Pack and Zometa when scripted. Strength: 3.75 mg/5 mg and 11.25 mg/5 mg vs. 4 mg

Proposed name: **Lupaneta Pack (Leuprolide Acetate and Norethindrone Acetate)** **Dosage Form(s):** **Injection and tablets** **Strength(s):** **3.75 mg/5 mg and 11.25 mg/5 mg** **Usual Dose: The Lupron component of the co-packaged kit is administered by intramuscular injection at the physician's office once a month (3.75 mg) or once every 3 months (11.25 mg) and the Norethindrone tablets will be taken orally once daily by the patient.**		**Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion** **Causes (could be multiple)** • **The modifier 'Pack' in the proposed name, Lupaneta pack may be omitted on a prescription order**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** • **If included, the modifier 'Pack' in the proposed name, Lupaneta pack may help differentiate this name**
28.	Supervite (Multivitamins and minerals) Tablets Usual Dose: One tablet orally daily or as directed.	Orthographic: Both names share similar scripted beginning letters ('L' vs. 'S') followed by the letter string '-up-' and similar scripted letter strings ('-an-' vs. '-er-'), similar position cross stroke 't' (seventh vs. eighth) followed by similar scripted vowels ('a' vs. 'e'). Partial Overlap in the Route of Administration and Dosage Form: Oral tablets Partial Overlap in the Usual Dose and Frequency of Administration: One tablet once daily	Strength: Multiple strengths (3.75 mg/5 mg and 11.25 mg/5 mg) vs. single strength

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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/

MANIZHEH SIAHPOUSHAN
10/25/2012

ZACHARY A OLESZCZUK
10/25/2012

KELLIE A TAYLOR
10/25/2012

KELLIE A TAYLOR on behalf of CAROL A HOLQUIST
10/25/2012