

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204426Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date: February 25, 2013

Reviewer: Manizheh Siahpoushan, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD
Division of Medication Error Prevention and Analysis

Drug Name(s) and Strength(s): Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol
Capsules and Ferrous Fumarate Capsules)
1 mg/20 mcg

Application Type/Number: NDA 204426

Applicant/sponsor: Warner Chilcott

OSE RCM #: 2013-512

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Minastrin 24 Fe is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Minastrin 24 Fe, acceptable in OSE Review #2012- 2277, dated December 11, 2012.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2012-2277. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases did not yield any new names thought to look or sound similar to Minastrin 24 Fe and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of February 25, 2013. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on February 20, 2013 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Minastrin 24 Fe, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Minastrin 24 Fe, for this product at this time.

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

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

4 REFERENCES

1. OSE Review #2012-2277, Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Proprietary Name Review; Siahpoushan, M. December 11, 2012.
2. **Drugs@FDA** (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)
Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved [brand name](#), [generic drugs](#), [therapeutic biological products](#), [prescription](#) and [over-the-counter](#) human drugs and [discontinued drugs](#) and “[Chemical Type 6](#)” approvals.
3. **USAN Stems** (<http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page?>)
USAN Stems List contains all the recognized USAN stems.
4. **Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request**
Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

/s/

MANIZHEH SIAHPOUSHAN
02/25/2013

ZACHARY A OLESZCZUK
02/25/2013

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

Proprietary Name Review

Date: December 11, 2012

Reviewer: Manizheh Siahpoushan, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Zachary Oleszczuk, PharmD
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl
Estradiol Capsules, and Ferrous Fumarate Capsules)
1 mg/20 mcg

Application Type/Number: NDA 204426

Applicant: Warner Chilcot, LLC

OSE RCM #: 2012-2277

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

This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through the FDA/CDER Office of Surveillance and Epidemiology.

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Minastrin 24 Fe, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Warner Chilcott, LLC submitted a New Drug Application under Section 505(b)(1) for Norethindrone Acetate and Ethinyl Estradiol Soft Gelatin Capsules, and Ferrous Fumarate Soft Gelatin Capsules on June 21, 2012. The Application provides for a new dosage form, Capsules, for oral contraception. The proposed regimen is the same as the approved regimen for Warner Chilcott's Loestrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Tablets, USP and Ferrous Fumarate Tablets) which received approval on February 17, 2006 under NDA 021871. The Applicant intends to discontinue marketing of Loestrin 24 Fe Tablets upon approval of the proposed product.

On September 27, 2012, the Applicant submitted a request for review of the proprietary name, Minastrin 24 Fe, for their proposed product. Additionally, this submission included labels and labeling which were reviewed under a separate cover in OSE Review #2012-1506 and 2012-2290.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 27, 2012 proprietary name submission.

- Active Ingredient: Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules
- Indication of Use: An estrogen and progestin combination oral contraceptive indicated for use by women to prevent pregnancy
- Route of Administration: Oral
- Dosage Form: Soft Gelatin Capsules
- Strength: 1 mg/20 mcg
- Dose and Frequency: One soft gelatin capsule by mouth at the same time every day for 28 days.
- How Supplied: A carton containing five blister cards of 28 capsules each. Each blister card contains 24 oval, transparent, pale yellow active capsules and 4 oval, opaque, maroon, non-hormonal placebo Ferrous Fumarate capsules
- Storage: Controlled room temperature
- Container and Closure Systems: Capsules are packaged in a (b) (4) blister film consisting of (b) (4) with (b) (4) aluminum (b) (4) lidding.

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 concurred with the findings of OPDP's promotional assessment of the proposed name. However, the Division of Reproductive and Urologic Products stated that the proposed name, Minastrin 24 Fe, may sound like "minimal estrogen" and could be considered promotional. DMEPA communicated the Division's concern to OPDP via e-mail on October 18, 2012. Per e-mail correspondence from OPDP on October 18, 2012, they maintained their non-objection position to Mianstrin 24 Fe, however, they did not provide any additional comments regarding their rationale. The Division had no further comments regarding the proposed name in the November 15, 2012 mid-cycle meeting. Additionally, DMEPA concurred with OPDP's final 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 9, 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

This proprietary name is comprised of the root name 'Minastrin' and the modifiers '24' and 'Fe'. The Applicant indicated in their submission that a derivation of the proposed proprietary name has not been determined. They further indicate that the modifier 'Fe' denotes the Ferrous Fumarate Soft Gelatin Capsules provided to complete a 28-day cycle, but did not indicate the intended meaning of the modifier '24'. However, the modifier '24' may denote that the product consists of 24 active pills. The RLD, Loestrin 24 Fe also contains the '24' and the 'Fe' modifiers for the same reasons.

Although the proposed proprietary name includes the modifiers '24' and 'Fe', the Applicant provided no data in their submission to support that the modifiers would not inadvertently introduce a source of error. However, the Applicant followed the same naming convention for the proposed name, Miastrin 24 Fe, as that of the RLD, and our October 1, 2012 FAERS search¹ did not identify any errors involving the misinterpretation of the modifiers '24' and 'Fe'. Additionally, the modifier 'Fe' has been used consistently and without error across all other oral contraceptive product lines that

¹ OSE Review #2012-1506 and 2012-2290, Minastrin 24 Fe Label and Labeling Review, Siahpoushan, M. November 5, 2012.

contain Ferrous Fumarate. Therefore, we find the inclusion of the modifiers ‘24’ and ‘Fe’ in conjunction with the root name, Minastrin, acceptable for this product.

2.2.3 FDA Name Simulation Studies

Eighty-five practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Thirty-four of the 85 participants (25 inpatient and 9 outpatient) interpreted the name correctly as ‘Minastrin 24 Fe’. Twelve participants (6 inpatient and 6 outpatient) interpreted the root name correctly as “Minastrin” but omitted the modifiers ‘24’ and ‘Fe’. Forty of the 85 participants (6 inpatient, 24 voice, and 10 outpatient) omitted the modifier ‘24’, and sixteen of the 85 participants (6 inpatient, 1 voice, and 9 outpatient) omitted both modifiers ‘24’ and ‘Fe’. 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) stated that the proposed name, Minastrin 24 Fe, may sound like “minimal estrogen” and could be considered promotional. See section 2.1 for discussion of this concern.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Minastrin 24 Fe. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Minastrin 24 Fe identified by the primary reviewer and the Expert Panel Discussion (EPD).

Table 1: Collective List of Potentially Similar Names (DMEPA and EPD)					
Look Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Loestrin 24 Fe	EPD	Lo Loestrin Fe	EPD	Menotropins	EPD
Westrim	PR	Mirena	EPD	Minocin	EPD
Mircette	EPD	Vivelle	PR	Mestinon	EPD
Vaseretic	EPD	Neurontin	EPD	Bacentra	EPD
Metastron	PR	Micatin	EPD	Norlestrin Fe	EPD
Maxivate	PR	Miacalcin	EPD	Microgestin Fe	EPD
Monistat	EPD	Momentum	EPD	Menostar	EPD

Table 1: Collective List of Potentially Similar Names (DMEPA and EPD)					
Menactra	EPD	Micaderm	EPD	Novantrone	EPD
Namenda	EPD	Mesantoin	EPD	Memantine	EPD
Vincristine	EPD	Nerventra***	PR	Nuvostro***	PR
Vasocidin	EPD	Masikan***	PR	Menest	EPD
Look and Sound Similar					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Minastrin	EPD	Miestrin	EPD	Minirin	EPD
Miniprin	EPD	Minitran	EPD		

Our analysis of the 38 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 38 names will not pose a risk for confusion as described in Appendices D through E.

2.2.6 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the Division of Reproductive and Urologic Products via e-mail on November 14, 2012. At that time we also requested additional information or concerns that could inform our review. In the mid-cycle meeting held on November 15, 2012, the Division of Reproductive and Urologic Products stated no additional concerns with the proposed proprietary name, Minastrin 24 Fe.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

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, Minastrin 24 Fe, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your September 27, 2012 submission are altered, 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.

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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.

¹ National Coordinating Council for Medication Error Reporting and Prevention. <http://www.nccmerp.org/about/MedErrors.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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 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 possess 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 and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Minastrin 24 Fe	Scripted May Appear as	Spoken May Be Interpreted as
Capital 'M'	W, U, V, N, ss	B, N
Lower case 'm'	m, mm, n, v, w, wi, vi, onc, z	b, n
Lower case 'i'	e, l	Any vowel
Lower case 'n'	m, u, x, r, h, s	dn, gn, kn, mn, pn, m
Lower case 'a'	'el', 'd', 'o', 'n', 'u'	Any vowel
Lower case 's'	G, 5, g, n,	x
Lower case 't'	r, f, x, A	d
Lower case 'r'	s, n, e, ,v	wr
Modifier '24'	zu, w, vi, ui or Modifier could be omitted during prescribing	Twenty for
Modifier 'Fe'	'Fc' or modifier could be omitted during prescribing	se
Capital 'F'	T	PF, Ph
Lower case 'e'	C, f, a, i, l, p	Any vowel and 'y'
Letter strings		
Mi	Vi, W	Me, Ma
in	ur, m,	m, d
tr	B	ter
ri	u, v	
in	ur, ui, w	im, id

Appendix C: Prescription Simulation Samples and Results

Figure 1. Minastrin 24 Fe Study (Conducted on 10/9/12)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u> Minastrin 24 Fe one tablet po daily</p>	<p>Minastrin 24 Fe 1 tab po qd #1 pack</p>
<p><u>Outpatient Prescription:</u> Minastrin 24 FE One tab po qd #1 pack</p>	

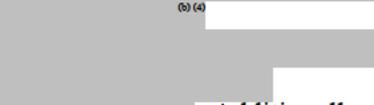
FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

192 People Received Study
85 People Responded

Study Name: Menastrin 24 FE

Total	32	24	29	
INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
MANASTRIN SE	0	3	0	3
MENASTERIN SE	0	1	0	1
MENASTRAN SE	0	1	0	1
MENASTRID SE	0	1	0	1
MENASTRIN	0	1	0	1
MENASTRIN FE	0	6	0	6
MENASTRIN SE	0	5	0	5
MINALTRIN 24 FE	0	0	1	1
MINASTRIN	6	0	6	12
MINASTRIN 24 EE	0	0	1	1
MINASTRIN 24 FE	22	0	5	27
MINASTRIN 24FE	3	0	4	7
MINASTRIN FE	0	0	1	1
MINASTRIN SE	0	5	0	5
MINASTRINE 24 FE	0	0	1	1
MINATRIN 24 FE	1	0	0	1
MINATSTRIN 24 FE	0	0	1	1
MINESTRAN FE	0	1	0	1
MINISTRIN 24 FE	0	0	1	1
MINOSTRIN	0	0	3	3
MINOSTRIN 24 FE	0	0	4	4
MINOSTRIN 24FE	0	0	1	1

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 Minastrin 24 Fe	Failure preventions
1.	Loestrin 24 Fe	Norethindrone Acetate, Ethinyl Estradiol and Ferrous Fumarate	Look	Trademark by Warner Chilcott (Same Applicant for the proposed proprietary name that is the subject of this review).   Additionally, the name pair lacks sufficient orthographic and/ or phonetic similarities.
2.	Lo Loestrin Fe	Norethindrone Acetate, Ethinyl Estradiol and Ferrous Fumarate	Look	The name pair lacks sufficient orthographic and/ or phonetic similarities.
3.	Menotropins	Established name for Menopur	Look	The name pair lacks sufficient orthographic and/ or phonetic similarities.
4.	Minastrin	Norethindrone Acetate, Ethinyl Estradiol and Ferrous Fumarate	Look and sound	Trademark by Warner Chilcott and the subject of this review.
5.	Minestrin	Norethindrone Acetate and Ethinyl Estradiol	Look and sound	Canadian brand name for Ethinyl Estradiol and Norethindrone. The Saegis database confirmed that the name, Minestrin, is a registered trademark by Warner and Chilcott (the Applicant for the product being evaluated in this review), Parke Davis, and Galen in several countries, but not the United States.
6.	Westrim	Phenylpropanolamine Hydrochloride	Look	Name identified only in the Redbook on line database with a 'deactivated' status. No other information could be obtained from any other available databases. The Saegis database identified the name, Westrim, as a registered trademark for non pharmaceutical products.

No.	Proprietary Name	Active Ingredient	Similarity to Minastrin 24 Fe	Failure preventions
7.	Mirena	Levonorgestrl	Look	The name pair lacks sufficient orthographic and/ or phonetic similarities
8.	Minirin	Desmopressin Acetate	Look and sound	The name pair lacks sufficient orthographic and/ or phonetic similarities.
9.	Minocin	Minocycline Hydrochloride	Look	The name pair lacks sufficient orthographic and/ or phonetic similarities.
10.	Mesantoin	Mephenytoin	Look	The application was withdrawn by the Federal Register effective 8/20/10 with no generic equivalents available. Additionally the usage database indicates that the product has not been prescribed since 2008.

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.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
1.	<p>Mircette (Desogestrel and Ethinyl Estradiol) Tablets 0.15 mg/0.02 mg and 0.01 mg</p> <p>Usual dose: One tablet by mouth daily.</p>	<p>Orthographic: Both names share the beginning letter string ‘Mi-’ followed by similar scripted letter strings (‘-na-’ vs. ‘-rce-’), and a sixth position upstroke ‘t’.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Strength: Single strength</p> <p>Frequency of Administration: Once daily</p> <p>Overlap in the Usual Dose: One (capsule vs. tablet) or may be prescribed ‘as directed’</p>	<p>Orthographic: The second upstroke ‘t’ in the seventh position of the name, Mircette (vs. the letter ‘r’ in Minastrin) and the additional ending letter ‘n’ in Minastrin provide different shapes and lengths for each name and can help differentiate Minastrin and Mircette when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
2.	<p>Vivelle (Estradiol) Transdermal System 0.025 mg/24 hrs; 0.0375 mg/24 hrs; 0.05 mg/24 hrs; 0.075 mg/24 hrs; 0.1 mg/24 hrs</p> <p>Usual dose: Apply one system topically twice a week.</p>	<p>Orthographic: Both names share similar scripted beginning letters (‘M’ vs. ‘V’) followed by the skinny letter ‘i’ , similar scripted letter strings (‘-na-’ vs. ‘-ve-’), and similar scripted sixth position upstrokes (‘t’ vs. ‘l’.</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. patch)</p>	<p>Orthographic: The fifth position upstroke ‘l’ in Vivelle and an additional two letters following the upstroke ‘t’ in Minastrin (vs. only one letter following the upstroke ‘l’ in Vivelle) provide different shapes and lengths for each name and can help differentiate Minastrin and Vivelle when scripted.</p> <p>Strength: Single strength (1 mg/20mcg) vs. multiple strengths (0.025 mg/24 hrs; 0.0375 mg/24 hrs; 0.05 mg/24 hrs; 0.075 mg/24 hrs; 0.1 mg/24 hrs)</p> <p>Frequency of Administration: Once daily vs. twice weekly</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
3.	<p>Mestinon (Pyridostigmine Bromide) Syrup, 60 mg/5 mL Tablets, 60 mg Extended-release Tablets, 180 mg</p> <p>Usual Dose: Syrup and conventional tablets: ten 60 mg tablets or ten 5 mL teaspoonfuls daily in divided doses. In severe cases as many as 25 tablets or teaspoonfuls a day may be required, while in mild cases one to six tablets or teaspoonfuls a day may suffice. Timespan tablets: One to three 180 mg tablets, once or twice daily.</p>	<p>Orthographic: Both names share the beginning letter ‘M’ followed by similar scripted letter strings (‘-in-’ vs. ‘-es-’, an upstroke ‘t’, and the letter string ‘-in’ after the upstroke ‘t’.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Solid oral (capsules vs. tablets)</p> <p>Possible Overlap in the Frequency of Administration: Once daily</p> <p>Parial Overlap in the Usual Dose: One (capsule vs. tablet or teaspoon)</p>	<p>Orthographic: The extra two letters (i.e. ‘a’ and ‘s’) preceding the upstroke ‘t’ in Minastrin provide a longer length for the letter string between the upstrokes ‘M’ and ‘t’ in Minastrin vs. Mestinon. Additionally, the extra round vowel ‘o’ in Mestinon provides a longer length for the letter string following the upstroke ‘t’ in Mestinon vs. Minastrin. Therefore, these differences can help differentiate Minastrin and Mestinon when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
4.	<p>Vaseretic (Enalapril Maleate and Hydrochlorothiazide) Tablets 5 mg/12.5 mg and 10 mg/25 mg</p> <p>Usual Dose: One to two tablets by mouth once daily.</p>	<p>Orthographic: Both names consist of nine letters, share similar scripted beginning letters (‘M’ vs. ‘V’), similar scripted letter strings in the same position of each name (‘-nas-‘ vs. ‘-ser-‘), similar position upstroke ‘t’ (sixth vs. seventh), and an eighth position skinny letter ‘i’.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet)</p>	<p>Orthographic: The extra letter ‘e’ preceding the upstroke ‘t’ in Vaseretic and the extra letter ‘r’ following the upstroke ‘t’ in Minastrin provide longer lengths for the letter string between the upstrokes ‘V’ and ‘t’ in Vaseretic (vs. the letter string between upstrokes ‘M’ and ‘t’ in Minastrin) and the letter string following the upstroke ‘t’ in Minastrin (vs. the letter string following the upstroke ‘t’ in Vaseretic) respectively, and can help differentiate Minastrin and Vaseretic when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (5 mg/12.5 mg or 10 mg/25 mg)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
5.	<p>Neurontin (Gabapentin) Capsules, 100 mg, 300 mg, 400 mg, Tablets, 600 mg, 800 mg Oral Solution, 250 mg/5 mL</p> <p><u>Usual Dose</u> 300 mg to 1200 mg up to 3 times daily. Renal impairment: If creatinine clearance is 30 mL/min to 59 mL/min: 200 mg to 700 mg orally twice daily, if 15 to 29 mL/min: 200 mg to 700 mg orally once daily, and if less than 15 mL/min: 100 mg to 300 mg orally once daily.</p>	<p>Orthographic: Both names consist of nine letters, share similar scripted beginning letters (‘M’ vs. ‘N’) followed by similar scripted vowels (‘i’ vs. ‘e’), similar scripted letter strings in similar positions of each name (‘-nas-’ vs. ‘-ron-’), similar position upstroke ‘t’ (sixth vs. seventh), and the ending letter string ‘-in’.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Usual Dose: Capsules</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Overlap in the Usual Dose: One capsule</p>	<p>Orthographic: The extra letter ‘u’ in Neurontin provides a longer length for the letter string between the upstrokes ‘N’ and ‘t’ in Neurontin (vs. the letter string between the upstrokes ‘M’ and ‘t’ in Minastrin). Additionally, the extra letter ‘r’ following the upstroke ‘t’ provides a longer length for the letter string following the upstroke ‘t’ in Minastrin (vs. the letter string following the upstroke ‘t’ in Neurontin) and can help differentiate Minastrin and Neurontin when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
6.	<p>Bacentra (Baclofen) Injection 50 mcg per mL, 500 mcg per mL, 2,000 mcg per mL</p> <p>Usual Dose: 12 mcg to 2,000 mcg continuous intrathecal infusion daily; 25 mcg to 100 mcg intrathecal bolus</p>	<p>Orthographic: Both names share the letter string ‘-tr-’ in the same position of each name, similar scripted letter strings in the same position of each name (‘-inas-’ vs. ‘-acen-’), and similar scripted ending letters (‘n’ vs. ‘a’).</p> <p>Overlap in the Frequency of Administration: Daily</p>	<p>Orthographic: The beginning letter ‘M’ does not appear similar to the beginning letter ‘B’ when scripted. Additionally, the additional eighth position skinny letter ‘i’ in minastrin provides a longer length for the letter string following the upstroke ‘t’ in Minastrin (vs. the letter string following the upstroke ‘t’ in Bacentra) and can help differentiate Minastrin and Bacentra when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (50 mcg/mL, 500 mcg/mL, or 2,000 mcg/mL)</p> <p>Dose: One tablet vs. 12 mcg to 2,000 or 25 mcg to 100 mcg</p>

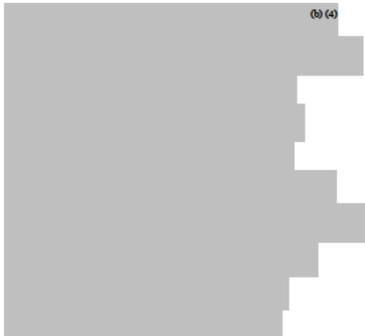
No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
7.	<p>Metastron (strontium Chloride, sr-89) Injection 148 MBq, 4mCi</p> <p>Usual Dose: 148 MBq, 4 mCi, administered by slow intravenous injection (1-2 minutes). Alternatively, a dose of 1.5 to 2.2 MBq/kg, 40 to 60 micro Ci/kg body weight may be used.</p>	<p>Orthographic: Both names consist of nine letters, share the beginning letter ‘M’ followed by similar scripted vowels (‘i’ vs. ‘e’), letter s tring ‘astr’ in the same position of each name, and the ending letter ‘n’.</p> <p>Strength: Single strength</p> <p>Overlap in the Frequency of Administration: Once</p> <p>Possible Partial Overlap in the Usual Dose: One (capsule vs. injection)</p>	<p>Orthographic: The third position upstroke ‘t’ in Metstron and the eighth position skinny letter ‘i’ in Minastrin (vs. the round vowel ‘o’ in Metastron) provide different shapes for each name and can help differentiate Minastrin and Metastron when scripted.</p> <p>Dose: One tablet vs. 1.5 to 2.2 MBq/kg, 40 to 60 micro Ci/kg or 148 MBq, 4 mCi</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
8.	<p>Micatin (Miconazole) Available as cream, powder, spray powder, or topical liquid, 2%</p> <p>Usual Dose: Apply twice daily for 4 weeks (or use as directed).</p>	<p>Orthographic: Both names share the beginning letter string ‘Mi-’, a fourth position letter ‘a’, similar position upstroke ‘t’ (sixth vs. fifth), and the ending letter string ‘-in’.</p> <p>Strength: Single strength</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. application) or may be prescribed ‘as directed’</p>	<p>Orthographic: The extra letter ‘s’ preceding the upstroke ‘t’ and the extra letter ‘r’ following the upstroke ‘t’ in Minastrin provide a longer length for this name and can help differentiate Minastrin and Micatin when scripted.</p>
9.	<p>Minitran (Nitroglycerin) Transdermal System 0.1 mg/hr; 0.2 mg/hr; 0.4 mg/hr; 0.6 mg/hr</p> <p>Usual dose: Apply one system to skin every 24 hours.</p>	<p>Orthographic/Phonetic: Both names share the beginning letter string ‘Min-’, similar position upstroke ‘t’ (sixth vs. fifth) followed by similar scripted ending letter strings (‘-rin’ vs. ‘-ran’). Phonetically, both names consist of 3 syllables, share the beginning sound ‘Mi’, and similar ending sounds (‘trin’ vs. ‘tran’).</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. patch or system)</p>	<p>Orthographic/Phonetic: The letter string ‘-as-’ preceding the upstroke ‘t’ in Minastrin (vs. the skinny letter ‘i’ in Minitran) provides a longer length for Minastrin and can help differentiate Minastrin and Minitran when scripted. Phonetically, the second syllables have different sounds (‘nas’ vs. ‘ni’) and can help differentiate the two names when spoken.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (0.1 mg/hr; 0.2 mg/hr; 0.4 mg/hr; 0.6 mg/hr)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
10.	<p>Maxivate (Betamethasone) Cream 0.05% and 0.1%</p> <p>Usual dose: Apply once or twice a day</p>	<p>Orthographic: Both names share the beginning letter ‘M’ followed by similar scripted letter strings (‘-ina-’ vs. ‘-axi-’, and similar position upstroke ‘t’ (sixth vs. seventh).</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. application)</p>	<p>Orthographic: The extra round letter ‘a’ preceding the upstroke ‘t’ in Maxivate provides a longer length for the letter string between the upstrokes ‘M’ and ‘t’ vs. Minastrin. Additionally, the extra two letters following the upstroke ‘t’ in Minastrin (vs. only one letter following the upstroke ‘t’ in Maxivate) provide a longer length for the letter string following the upstroke ‘t’ in Minastrin and can help differentiate Minastrin and Maxivate when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (0.05% and 0.1%)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
11.	<p>Miacalcin (Calcitonin Salmon) Injection, 200 units/mL Spray, 200 units per actuation</p> <p>Usual Dose: Nasal spray: one spray (200 units) per day administered intranasally, alternating nostrils daily. Injection: <u>Paget’s disease:</u> 50 units to 100 units (0.5 mL) subcutaneously daily or every other day. <u>Hypercalcemia:</u> 4 units/kg every 12 hours by subcutaneous or intramuscular injection. After one or two days, the dose may be increased to 8 units/kg every 12 hours. <u>Postmenopausal osteoporosis:</u> 100 units subcutaneously or intramuscularly every other day.</p>	<p>Orthographic: Both names share consist of nine letters, share the beginning letter strings ‘Mi-’ followed by similar scripted letter strings (‘-nas-’ vs. ‘-aca-’) followed by an upstroke (‘t’ vs. ‘l’), and ending letter string ‘-in’.</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. spray)</p>	<p>Orthographic: The letter string ‘-nas’ in Minastrin appears different than the letter string ‘-aca-’ in Miacalcin when scripted. Additionally, the seventh position letter ‘r’ in Minastrin (vs. the seventh position letter ‘c’ in Miacalcin) provides a different appearance and a longer length for the ending letter string ‘-rin’ (vs. ‘-cin’ in Miacalcin) when scripted and can help differentiate Minastrin and Miacalcin when scripted.</p> <p>Additionally, a prescriber would have to indicate one or more of the following on a Miacalcin prescription in order for a pharmacist to be able to fill the prescription: Dosage form (injection or nasal spray), dose (i.e. 1 spray or 50 to 200 units). Therefore, the risk of medication error due to confusion between Minastrin and Miacalcin can be minimized.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
12.	<p>Microgestin Fe (Norethindrone Acetate and Ethinyl Estradiol and Ferrous Fumarate) Tablets 1/20 and 1.5/30</p> <p>Usual Dose: One tablet orally once daily.</p>	<p>Orthographic: Both names share the beginning letter string ‘Mi-’, similar scripted letter strings in similar positions (‘-na-’ vs. ‘-ro-’), letter string ‘-st-’ preceded by similar scripted round vowels (‘a’ vs. ‘e’), ending letter string ‘-in’, and the modifier ‘Fe’ (if included on a prescription order).</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Overlap in the Strength: 1 mg/20 mcg</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet) or may be prescribed ‘as directed’</p>	<p>Orthographic: The downstroke ‘g’ preceded by the extra letter string ‘-ro-’ in Microgestin provide a different shape and a longer length for the letter string between the upstrokes ‘M’ and ‘t’ in Microgestin vs. Minastrin. Additionally, the extra letter ‘r’ following the upstroke ‘t’ in Minastrin provides a longer length for the letter string following the upstroke ‘t’ in this name vs. Microgestin and can help differentiate Minastrin and Microgestin when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
13.	<p>Norlestrin Fe (Norethindrone Acetate, Ethinyl Estradiol and Ferrous Fumarate) Tablets, 1/50 and 2.5/50</p>  <p>Usual Dose: One tablet orally once daily.</p>	<p>Orthographic: Both names share similar scripted beginning letters (‘M’ vs. ‘N’), similar scripted letters in the third position (‘n’ vs. ‘r’), the ending letter string ‘-strin’ preceded by similar scripted vowels (‘a’ vs. ‘e’), and the modifier ‘Fe’ (if included on a prescription order).</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet) or may be prescribed ‘as directed’</p>	<p>Orthographic: The upstroke ‘l’ in Norlestrin Fe provides a different shape and a longer length for this name and can help differentiate Minastrin and Norlestrin when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (1/50 or 2.5/50)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
14.	<p>Miniprin (Aspirin) Enteric Coated Tablets, 81 mg</p> <p>Usual Dose: Adults: 3 grams per day or less in divide doses. Children: 90 to 130 mg/kg/day in divided doses.</p>	<p>Orthographic/Phonetic: Both names share the beginning letter string ‘Min-‘ and the ending letter string ‘-rin’. Phonetically, both names consist of 3 syllables, share the same sound in the first syllable and similar sounds in the last syllable (‘trin’ vs. ‘prin’) when spoken.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Strength: Single strength</p> <p>Possible Overlap in the Frequency of Administration or the Usual Dose: One daily</p>	<p>Orthographic/Phonetic: The downstroke ‘p’ in Miniprin and the upstroke ‘t’ in Minastrin provide different shapes for each name and can help differentiate Minastrin and Miniprin when spoken. Orthographically, the second syllable of each name sound different (‘nas’ vs. ‘ni’) and can help differentiate the two names when spoken.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
15.	<p>Menest (Esterified Estrogens) Tablets, 0.3 mg, 0.625 mg, 1.25 mg, 2.5 mg</p> <p>Usual Dose: One tablet orally once daily (the length of therapy may vary depending on the type of treatment).</p>	<p>Orthographic: Both names share the beginning letter ‘M’ followed by similar scripted vowels (‘i’ vs. ‘e’), a third position letter ‘n’ followed by similar scripted vowels (‘a’ vs. ‘e’), and the letter string ‘-st’.</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet)</p>	<p>Orthographic: The extra ending letter string ‘-rin’ following the upstroke ‘t’ in Minastrin (vs. no additional letter strings following the upstroke ‘t’ in Menest) provides a longer length for this name and can help differentiate Minastrin and Menest when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (0.3 mg, 0.625 mg, 1.25 mg, and 2.5 mg)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
16.	<p>Monistat (Miconazole) Available as Monistat 1, Monistat 3, or Monistat 7 Vaginal cream, 2% or 4% vaginal inserts, 100 mg, 200 mg, or 1200 mg</p> <p>Usual Dose: Vaginal cream: insert one applicatorful at bedtime for 3 or 7 days Suppositories: insert one suppository at bedtime for 1, 3, or 7 days.</p>	<p>Orthographic: Both names share the beginning letter ‘M’, a third position letter ‘n’, and the letter string ‘-st-’ in the same position of each name.</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. application or suppository) or may be prescribed ‘as directed’</p>	<p>Orthographic: The ending upstroke ‘t’ in Monistat provides a different shape for this name and can help differentiate Minastrin and Monistat when scripted.</p>
17.	<p>Momentum (Magnesium Salicylate) Caplets 580 mg</p> <p>Usual Dose: Two caplets every 6 hours as needed.</p>	<p>Orthographic: Both names share the beginning letter ‘M’, similar scripted letter strings in the same position (‘-as-’ vs. ‘-en-’) followed by a sixth position upstroke ‘t’, and similar scripted ending letter string and letter in each name (‘-in’ vs. ‘m’).</p> <p>Route of Administration: Oral</p> <p>Dosage Form: Solid oral</p> <p>Strength: Single strength</p>	<p>Orthographic: The letter string ‘-in-’ in Minastrin appears different than the letter string ‘-om-’ in Momentum and can help differentiate Minastrin and Momentum when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
18.	<p>Menostar (Estradiol) Patch 14 mcg per day</p> <p>Usual Dose: Apply one patch once weekly (or use as directed).</p>	<p>Orthographic: Both names share the beginning letter ‘M’ followed by similar scripted vowels (‘i’ vs. ‘e’), a third position letter ‘n’ followed by similar scripted round vowels (‘e’ vs. ‘o’), and the same position letter string ‘-st-’.</p> <p>Strength: Single strength</p> <p>Overlap in the Frequency of Administration: Once</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. patch) or may be prescribed ‘as directed’</p>	<p>Orthographic: The extra eighth position skinny letter ‘i’ in Minastrin provides a longer length for the letter string following the upstroke ‘t’ vs. Menostar and can help differentiate Minastrin and Menostar when scripted.</p>
19.	<p>Menactra (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) Injection Supplied in 0.5 mL single dose vials</p> <p>Usual Dose: A 0.5 mL dose for intramuscular injection. Children 9 through 23 months of age: Two doses, three months apart. Individuals 2 through 55 years of age: A single dose.</p>	<p>Orthographic: Both names share the beginning letter ‘M’ followed by similar scripted vowels (‘i’ vs. ‘e’), a third position letter ‘n’ followed by similar scripted round vowels (‘e’ vs. ‘a’), and the same position letter string ‘-tr-’.</p> <p>Strength: Single strength</p> <p>Partial Overlap in the Frequency of Administration: Once</p>	<p>Orthographic: The extra eighth position skinny letter ‘i’ in Minastrin provides a longer length for the letter string following the upstroke ‘t’ vs. Menactra and can help differentiate Minastrin and Menactra when scripted.</p> <p>Dose: The dosage of Menactra (0.5 mL) and Minastrin (one capsule) do not overlap and are not achievable</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
20.	<p>Micaderm (Miconazole) Cream, 2%</p> <p>Usual Dose: Apply topically twice daily for four weeks (or use as directed).</p>	<p>Orthographic: Both names share the beginning letter string ‘Mi-’, a fourth position letter ‘a’, and similar scripted ending letter strings (‘-rin’ vs. ‘-rm’).</p> <p>Strength: Single strength</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. application) or may be prescribed ‘as directed’</p>	<p>Orthographic: The letter string ‘-st-’ in Minastrin appears different than the letter ‘d’ in Micaderm and can help differentiate Minastrin and Micaderm when scripted.</p>
21.	<p>Novantrone (Mitoxantrone HCL) Injection</p> <p>(NDA 019297 withdrawn FR effective 4/18/12 not for safety reasons)</p> <p>Usual Dose: <u>Multiple sclerosis:</u> 12 mg/m² given as a short intravenous infusion every 3 months. <u>Hormone refractory prostate cancer:</u> 12 to 14 mg/ m² as a short intravenous infusion every 21 days. <u>Combination initial therapy for ANLL in adults:</u> 12 to 14 mg/ m² daily on days 1 to 3 intravenously.</p>	<p>Orthographic: Both names share similar scripted beginning letters (‘M’ vs. ‘N’), a fourth position letter ‘a’ followed by similar scripted letters (‘s’ vs. ‘n’, same position letter string ‘-tr-’, and and a ninth position letter ‘n’.</p> <p>Strength: Single strength</p> <p>Overlap in the Frequency of Administration: Daily</p>	<p>Orthographic: The second and eighth position letter ‘o’ in Novantrone (vs. the second and eighth position skinny letter ‘i’ in Minastrin) and the extra ending letter ‘e’ in Novantrone provide a different shape and a longer length for Novantrone and can help differentiate Minastrin and Novantrone when scripted.</p> <p>Dose: One tablet vs. 12 mg/ m² to 14 mg/ m²</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
22.	<p>Namenda (Memantine Hydrochloride) Tablets, 5 mg and 10 mg Oral Solution, 2 mg/mL</p> <p>Usual Dose: 5 to 20 mg orally per day once or twice daily.</p>	<p>Orthographic: Both names share similar scripted beginning letters (‘M’ vs. ‘N’), similar scripted letter strings in the same position of each name (‘-as-’ vs. ‘-en-’) followed by an upstroke (‘t’ vs. ‘d’), and similar scripted ending letters (‘n’ vs. ‘a’). Additionally, the letter string ‘-in-’ in the second and third position of the name Minastrin may appear similar to the letter ‘m’ in Namenda when scripted.</p> <p>Route of Administration: Oral</p> <p>Overlap in the Dosage Form: Solid oral</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet)</p>	<p>Orthographic: The extra letter string ‘-ri-’ following the upstroke ‘t’ in Minastrin provides a different shape for this name and can help differentiate Minastrin and Namenda when scripted.</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
23.	<p>Memantine (Established name for Namenda) Tablets, 5 mg and 10 mg Oral Solution, 2 mg/mL</p> <p>Usual Dose: 5 to 20 mg orally per day once or twice daily.</p>	<p>Orthographic: Both names consist of nine letters, share the beginning letter ‘M’ followed by similar scripted letter strings (‘-inast- vs. ‘-emant-‘), and the letter string ‘-in’ in similar positions of each name (following the upstroke ‘t’).</p> <p>Route of Administration: Oral</p> <p>Overlap in the Frequency of Administration: Once daily</p> <p>Partial Overlap in the Usual Dose: One (capsule vs. tablet)</p>	<p>Orthographic: The ending letter ‘e’ in Memantine appears different than the ending letter ‘n’ in Minastrin and can help differentiate Minastrin and Memantine when scripted.</p> <p>Strength: Single strength (1 mg/20 mcg) vs. multiple strengths (5 mg and 10 mg)</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules) Dosage Form: Soft Gelatin Capsules Strength: 1 mg/20 mcg Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>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</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
24.	<p>Vincristine (Established name for Vincasar) Injection, 1 mg/mL</p> <p>Usual Dose: Pediatric patients: 1.5 to 2 mg/m². if 10 kg or less, the starting dose should be 0.05 mg/kg once a week. Adults: 1.4 mg/m².. A 50% reduction in the dose of is recommended for patients having a direct serum bilirubin value above 3 mg/100 mL.</p>	<p>Orthographic: Both names share similar scripted beginning letter string (‘M’ vs. ‘V’) followed by similar scripted letter strings (‘-ina-’ vs. ‘-inc-’), letter strings ‘-st-’, and ‘-in’ (following the upstroke ‘t’).</p> <p>Strength: Single strength</p> <p>Partial Overlap in the Frequency of Administration: Once</p>	<p>Orthographic: The extra letter string ‘-ri-’ provides a longer length for the letter string between the upstrokes ‘V’ and ‘t’ in Vincristine (vs. the letter string between the upstrokes ‘M’ and ‘t’ in Minastrin). Additionally, the ending letter ‘e’ in Vincristine appears different than the ending letter ‘n’ in Minastrin and can help differentiate Minastrin and Vincristine when scripted.</p> <p>Dose: One tablet vs. dosing based on body surface area</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may help differentiate this name
25.			

03/09

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No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may help differentiate this name
26.			

03/03

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No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers ‘24’ and ‘Fe’ in the proposed name, Minastrin 24 Fe may help differentiate this name
27.	<p>Vasocidin (Prednisolone Sodium Phosphate and Sulfacetamide Sodium) Ophthalmic Drops 0.23%/10%</p> <p>Usual Dose: Two drops to the affected eye(s) every 4 hours.</p>	<p>Orthographic: Both names consist of nine letters, share similar scripted beginning letters (‘M’ vs. ‘V’) followed by similar scripted letter strings (‘-inas-’ vs. ‘aso-’), a similar position upstroke (sixth position ‘t’ vs. seventh position ‘d’), and the ending letter string ‘-in’.</p> <p>Strength: Single strength</p>	<p>Orthographic: The extra letter ‘r’ following the upstroke ‘t’ in Minastrin provides a longer length for the letter string following the upstroke ‘t’ (vs. the letter string following the upstroke ‘d’ in Vasocidin). Additionally, the extra skinnily letter ‘i’ and the round portion of the upstroke ‘d’ provide a longer length for the letter string between the upstrokes ‘V’ and ‘d’ in Vasocidin (vs. the letter string between the upstrokes ‘M’ and ‘t’ in Vasocidin) and can help differentiate Minastrin and Vasocidin when scripted.</p> <p>Usual Dose: One tablet vs. two drops</p>

No.	<p>Proposed name: Minastrin 24 Fe (Norethindrone Acetate and Ethinyl Estradiol Capsules and Ferrous Fumarate Capsules)</p> <p>Dosage Form: Soft Gelatin Capsules</p> <p>Strength: 1 mg/20 mcg</p> <p>Usual Dose: One capsule orally once daily.</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p> <ul style="list-style-type: none"> • The modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may be omitted on a prescription order 	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p> <ul style="list-style-type: none"> • If included, the modifiers '24' and 'Fe' in the proposed name, Minastrin 24 Fe may help differentiate this name
28.			

03/03

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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
12/11/2012

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12/11/2012

CAROL A HOLQUIST
12/12/2012