CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204654Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review

Date:	July 9, 2013
Reviewer:	Manizheh Siahpoushan, PharmD Division of Medication Error Prevention and Analysis
Acting Team Leader:	James Schlick, RPh, MBA Division of Medication Error Prevention and Analysis
Division Director:	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Lo Minastrin Fe (Norethindrone Acetate and Ethinyl Estradiol Chewable Tablets, Ethinyl Estradiol Tablets, and Ferrous Fumarate Tablets) 1 mg/10 mcg and 10 mcg and 75 mg
Application Type/Number:	NDA 204654
Applicant/Sponsor:	Warner Chilcott
OSE RCM #:	2013-1522

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Lo Minastrin 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 request for proprietary name review for Lo Minastrin Fe (Norethindrone Acetate and Ethinyl Estradiol Chewable Tablets, Ethinyl Estradiol Tablets, and Ferrous Fumarate Tablets) for NDA 204654 on June 27, 2013. The first proposed proprietary name, (b) (4) was found unacceptable in OSE Review #2013-860 dated June 12, 2013.

The New Drug Application for this product was submitted by the Applicant under Section 505(b)(1) on September 28, 2012. This NDA provides for a new method of administration for low dose oral contraception consisting of mint-flavored, chewable tablets. The proposed regimen is the same as the approved regimen for Lo Loestrin Fe (NDA 022501, approved October 21, 2010) by Applicant holder, Warner Chilcott LLC. The main difference with NDA 204654 is that the first 24 active tablets may be chewed before swallowing and followed with liquid (b) (4). Once approved, the Applicant plans to discontinue Lo Loestrin Fe.

Additionally, the Applicant submitted labels and labeling on June 27, 2013 which will be reviewed by DMEPA under a separate cover in OSE Review #2013-1-1.

1.2 PRODUCT INFORMATION

The following product information is provided in the June 27, 2013 proprietary name submission.

- Active Ingredient: Norethindrone Acetate and Ethinyl Estradiol Chewable Tablets, Ethinyl Estradiol Tablets and Ferrous Fumarate Tablets
- Indication of Use: Prevention of Pregnancy
- Route of Administration: Oral
- Dosage Form: Chewable Tablets and Tablets
- Strength: 1 mg/10 mcg, 10 mcg, and 75 mg
- Dose and Frequency: Take one tablet by mouth at the same time every day. The blue tablet may be (b) (4) chewed and swallowed. If the blue tablet is chewed, the patient should drink a full glass (8 ounces) of liquid immediately after swallowing. The white tablet and the brown tablet are swallowed.
- How Supplied: Carton of 5 blister cards; each blister card contains 24 blue, round (active) chewable tablets containing 1 mg norethindrone and 10 mcg ethinyl estradiol, 2 white hexagonal (active) tablets containing 10 mcg ethinyl estradiol, and 2 brown, round (non-hormonal placebo) tablets containing 75 mg ferrous fumarate.

- Storage: Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F)
- Container and Closure System: Primary packaging consists of unit-dose blisters consisting of (b) (4) blister film and an aluminum foil/vinyl heat-seal coated lidding. Secondary packaging consists of a rigid (b) (4) card bonded to the unit-dose blister, prescriber and patient package inserts, and (b) (4) board cartons.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) SEARCH

The June 28, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proprietary name is comprised of the root name 'Minastrin' and the modifiers 'Lo' 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 'Lo' denotes the low dose of estrogen in this product, and the modifier 'Fe' denotes the Ferrous Fumarate tablets (non-hormonal) provided to complete a 28-day cycle.

The Applicant did not provide data to support the use of these modifiers, nor provide data to support that these modifiers would not inadvertently introduce a source of error. However, the Applicant followed the same naming convention for the proposed name, Lo Minastrin Fe, as that of the reference listed drug, Lo Loestrin Fe.

The 'Fe' modifier in oral contraceptive products has consistently meant 75 mg of Ferrous Fumarate. The Applicant is proposing to use the modifier 'Fe' consistently with how it is used in the reference listed drug. Similarly, the 'Lo' modifier is used for other approved oral contraceptive products to represent lower estrogen content or lower estrogen and progestin content. The Applicant is proposing to use the modifier 'Lo' consistently with how it is used in the reference listed drug, and the amount of Ethinyl Estradiol in the proposed product, Lo Minastrin Fe is indeed less than that found in the Applicant's other proposed Minastrin product (i.e., Minastrin 24 Fe***) which is currently under review by the Agency. Additionally, DMEPA has previously reviewed and permitted the modifiers 'Lo' and 'Fe' into the marketplace in the past. Table 1 provides a comparison of Warner Chilcott's Loestrin product line as well as their new proposed products, Minastrin 24

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