CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022501Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	October 8, 2010
Application Type/Number:	NDA 022501
To:	Scott Monroe, M.D., Director Division of Reproductive and Urologic Products
Through:	Zachary Oleszczuk, Pharm.D., Team Leader Denise Toyer, Pharm.D., Deputy Director Division of Medication Error Prevention and Analysis
From:	Tara Turner, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name, Label and Labeling Review
Drug Name(s):	Lo Loestrin Fe (Norethindrone Acetate and Ethinyl Estradiol Tablets, 1 mg/10 mcg Ethinyl Estradiol Tablets, 10 mcg and Ferrous Fumarate Tablets, 75 mg)
Applicant:	Warner Chilcott
OSE RCM #:	2010-1184 and 2009-652

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Lo Loestrin 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, Lo Loestrin Fe, acceptable in OSE Review #2009-2349, dated January 19, 2010. DDMAC reviewed the proposed name on December 17, 2009, and had no concerns regarding the proposed name from a promotional perspective. Furthermore, the Review Division did not have any concerns with the proposed name, Lo Loestrin Fe, during our initial review.

The Applicant received a complete response action for this NDA on January 26, 2010. The Applicant submitted a class 2 response on April 21, 2010. As part of that response, the Applicant submitted revised container labels, carton and insert labeling, which are also the subject of the current review. During the initial review cycle of this NDA, DMEPA completed a review of the Applicant's proposed labels and labeling in OSE Review #2009-652, dated January 14, 2010.

2 METHODS AND RESULTS

2.1 PROPRIETARY NAME

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria used in OSE Review #2009-2349 for the proposed proprietary name, Lo Loestrin Fe. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the United States Adopted Names (USAN) stem list to determine if the name contains any USAN stems as of the last USAN update. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors. As in the previous proprietary name review, DMEPA staff identified a United States Adopted Names (USAN) stem in the proposed proprietary name, as of October 4, 2010. The stem is -estr-, which represents estrogens.

The searches of the databases yielded no new names thought to look or sound similar to Lo Loestrin Fe and represent a potential source of drug name confusion.

2.2 LABELS AND LABELING

The Applicant submitted revised container labels (see Appendix A), carton (see Appendix B), and insert labeling on April 21, 2010. DMEPA used Failure Mode and Effects Analysis (FMEA) and the principles of Human Factors in our evaluation of the labels and labeling. We also reviewed the labeling recommendations presented in OSE Review #2009-652, dated January 14, 2010 to determine if our recommendations had been incorporated into the revised labels and labeling.

3 DISCUSSION

3.1 PROPRIETARY NAME

As noted in the previous proprietary name review of Lo Loestrin Fe, the root name, Loestrin, contains the USAN stem -estr-, which represents estrogens. Inclusion of a USAN stem in a proprietary name is typically unacceptable. However, in this case since the root name was approved in 1973, the presence of the USAN stem alone would not render the name unacceptable.

3.2 LABELS AND LABELING

The Applicant revised the labels and labeling and incorporated most of DMEPA's recommendations. However, changes in the presentation of the proprietary name and the product strength pose additional concerns.

4 CONCLUSIONS AND RECOMMENDATIONS

4.1 PROPRIETARY NAME

This re-review determined that the proposed name, Lo Loestrin Fe, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Lo Loestrin 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.

4.2 LABELS AND LABELING

Our evaluation noted areas where the presentation of information on the container labels, carton and insert labeling can be improved to minimize the potential for medication errors. We provide recommendations for all product labels and labeling in *Section 4.2.1 Comments to the Division* for discussion during the review team's label and labeling meetings. *Section 4.2.2 Comments to the Applicant* contains our recommendations for the container labels and carton labeling. We request the recommendations in Section 4.2.2 be communicated to the Applicant prior to approval.

Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact Maria Wasilik, Project Manager, at 301-796-0567.

4.2.1 Comments to the Division

A. General Comments for All Labels and Labeling

1. As stated in our previous review, we defer to the clinical review team for a decision regarding inclusion of the statement "Lo Loestrin Fe provides 26 days of active therapy" since it is unclear whether the 2 tablets containing ethinyl estradiol alone provide oral contraceptive efficacy. If the statement is included, it should be presented with less prominence than the proprietary name, established name, and product strength.
2. Consider revising the font used to present the proprietary name. As currently presented, the font is fanciful and may be difficult to read, especially the capital letter 'F', which may be confused as a capital letter 'T'.

4.2.2 Comments to the Applicant

A. Container Labels: Blister Card: Trade and Sample (28 tablets)

1. Remove the (b) (4) separating the proprietary name from the established name as this line is considered intervening matter and violates 21 CFR 201.10(a).
2. Increase the prominence of the proprietary name. As currently presented, it has less prominence than the manufacturer's logo.

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