CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204654Orig1s000

PHARMACOLOGY REVIEW(S)



Division of Reproductive and Urologic Products Center for Drug Evaluation and Research

Date: 5/16/2013

Reviewer: Alex Jordan, PhD

NDA #/SS#/date: 204654

Sponsor: Warner Chilcott

Drug Product: Norethindrone acetate/ethinyl estradiol/FE tablets

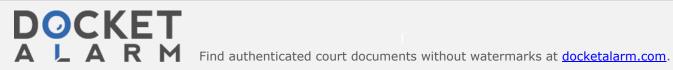
Indication: Contraception

Recommended Action: Approval

Background: I agree with the primary reviewer Dr. Raheja that NDA 204654 is approvable for contraception from a pharmacology standpoint.



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/s/
ALEXANDER W JORDAN 05/16/2013



DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA/BLA REVIEW AND EVALUATION

Application number: 204654

Supporting document/s: e-submission

Applicant's letter date: 9/27/2012

CDER stamp date: 9/28/2012

Product: Norethindrone acetate NA) / Ethinyl estradiol

(EE)/FE tablets

Indication: Prevention of pregnancy

Applicant: Warner Chilcott

Review Division: RUDP

Reviewer: Krishan L. Raheja, D.V.M., Ph.D.

Supervisor/Team Leader: Alex Jordan, Ph.D.

Division Director: Hylton, Joffe, M.D. MMSc

Project Manager: Pamela K. Lucarelli

Review entered in DARRTS: 4/19/2013

Disclaimer

Except as specifically identified, all data and information discussed below and necessary for approval of NDA 204654 are owned by Warner Chilcott or are data for which Warner Chilcott has obtained a written right of reference.

Any information or data necessary for approval of NDA 204654 that Warner Chilcott does not own or have a written right to reference constitutes one of the following: (1) published literature, or (2) a prior FDA finding of safety or effectiveness for a listed drug, as reflected in the drug's approved labeling. Any data or information described or referenced below from reviews or publicly available summaries of a previously approved application is for descriptive purposes only and is not relied upon for approval of NDA 204654.



1 Executive Summary

- 1.2 Brief Discussion of Nonclinical Findings: All nonclinical pharmacology/toxicology information referred to sponsor's approved NDA 022501 for Lo Loestrin Fe.
- 1.3 Recommendations:
- **1.3.1 Approvability:** Pharmacology/Toxicology recommends approval of under NDA 204654 for the indication of prevention of pregnancy
- 1.3.2 Additional Non Clinical Recommendations: None
- **1.3.3 Labeling:** Sponsor has provided drug label in PLR format which is acceptable from the Pharmacology/Toxicology perspective.

2 Drug Information

2.1 Drug

CAS Registry Number (Optional)

For norethindrone acetate CAS number: 51-98-9 For ethinyl estradiol CAS number: 57-63-6

Generic Name: Norethindrone acetate, ethinyl estradiol, ferrous fumarate

Code Name: (b) (4)



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