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APPLICATION NUMBER:

204654Orig1s000

PHARMACOLOGY REVIEW(S)

MEMO **FOOD AND DRUG ADMINISTRATION**

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.

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

/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 (b) (4)
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*

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1 Executive Summary

1.1 Introduction: This NDA provides for a new method of administration for a low dose oral contraceptive consisting of one chewable tablet containing 1 mg norethindrone acetate and 10 ug ethinyl estradiol ((b) (4) 1/10 chewable tablets) taken daily for 24 days followed by one tablet containing 10 ug ethinyl estradiol alone taken daily for 2 days, and one ferrous fumarate tablet taken daily for 2 days to facilitate 28-day regimen. (b) (4) 1/10 chewable tablets may be (b) (4) chewed before swallowing and followed with liquid; the 4 remaining tablets are swallowed. In lieu of nonclinical pharmacology and toxicology information, this application makes reference to sponsor's NDA 022501 approved on 10/20/2010 for Lo Loestrin Fe which consists of the same regimen and daily doses of active ingredients as in (b) (4) but in which all 28 tablets are swallowed.

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 (b) (4) 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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