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APPLICATION NUMBER:

204654Orig1s000

MEDICAL REVIEW(S)

CLINICAL REVIEW

Application Type	NDA
Application Number(s)	204654
Priority or Standard	Standard
Submit Date(s)	September 27, 2012
Received Date(s)	September 28, 2012
PDUFA Goal Date	July 28, 2013
Division / Office	DBRUP/ODE III
Reviewer Name(s)	Daniel Davis, MD
Review Completion Date	June 28, 2013
Established Name	norethindrone acetate/ethinyl estradiol (EE) chewable tablets, ethinyl estradiol tablets and ferrous fumarate (FF) tablets
(Proposed) Trade Name	to be determined
Therapeutic Class	Hormonal contraception
Applicant	Warner Chilcott Company, LLC
Formulation(s)	Chewable tablet; tablet
Dosing Regimen	1 active chewable tablet for 24 days; 1 EE tablet for 2 days; 1 iron tablet for 2 days
Indication(s)	Prevention of pregnancy
Intended Population(s)	Women of reproductive age

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List of Abbreviations and Definitions

AE	Adverse event
BMI	Body mass index
CI	Confidence interval
CHC	Combination hormonal contraceptive
COC	Combination oral contraceptive
DBRUP	Division of Bone, Reproductive and Urologic Products
EE	Ethinyl estradiol
FDA	Food and Drug Administration
FF	Ferrous fumarate
GCP	Good clinical practice
NETA	Norethindrone acetate
NDA	New Drug Application
NE	Norethindrone
OC	Oral contraceptive
ODE III	Office of Drug Evaluation III
OSI	Office of Scientific Investigation
PI	Pearl Index
SAE	Serious adverse event
VTE	Venous thromboembolism

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