CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204654Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA#:	204654/N0000
Drug Name:	(b) (4) (norethindrone acetate and ethinyl estradiol chewable tablets, ethinyl estradiol chewable tablets and ferrous fumarate tablets)
Indication(s):	Prevention of pregnancy
Applicant:	Warner Chilcott (US),
Date(s):	Submission Date: 09/28/2012
	PDUFA Due Date: 07/28/2013
Review Priority:	Standard
Biometrics Division:	Division of Biometrics 3
Statistical Reviewer:	Xin Fang, Ph.D., Statistical Reviewer
Concurring Reviewers:	Mahboob Sobhan, Ph.D., Statistical Team Leader
Medical Division:	Division of Bone, Reproductive and Urologic Drug Products
Clinical Team:	Daniel Davis, MD., Clinical Reviewer
	Lisa Soule, MD., Clinical Team Leader
Project Manager:	Pamela Lucarelli

Keywords: Bioavailability, NDA, Review, Clinical Studies

BACKGROUND

The Applicant, Warner Chilcott (US) LLC, submitted a 505(b)(1) NDA application for [redacted] in the prevention of pregnancy. The efficacy and safety data were referred to the Applicant's NDA 022501 for [redacted]

The Applicant has developed a new method of administration for low dose oral contraception consisting of one mint-flavored, chewable tablet (1 mg norethindrone acetate (NA) and 10 mcg ethinyl estradiol (EE)) daily for 24 days followed by one tablet containing 10 mcg EE alone daily for 2 days, and one ferrous fumarate tablet daily for 2 days, for a total of 28 days. The chewable tablets can be swallowed with liquid.

The Applicant provided comparative bioavailability data and an oral irritation safety report in support of this application.

CONCLUSION

There were no new efficacy data submitted in support of this submission. Therefore, no statistical review was necessary.

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/s/

XIN FANG
05/28/2013

MAHBOOB SOBHAN
06/04/2013

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 204-654/0000 **Applicant:** Warner Chilcott (US), LLC **Stamp Date:** 09/28/2012

Drug Name: (b) (4) **NDA/BLA Type:** Original/Standard **Indication:** Contraceptive

On **initial** overview of the NDA/BLA application for RTF:

	Content Parameter	Yes	No	NA	Comments
1A	Paper Submission: Index is sufficient to locate necessary reports, tables, data, etc.			X	
1B	Electronic Submission: Indexing and reference links within the electronic submission are sufficient to permit navigation through the submission, including access to reports, tables, data, etc.	X			
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)			X	505(b)(1)
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated.			X	
4	Data sets in EDR are accessible and conform to applicable guidances (e.g., existence of define.pdf file for data sets).	X			

IS THE STATISTICAL SECTION OF THE APPLICATION FILEABLE? ___YES_____

Content Parameter (possible review concerns for 74-day letter)	Yes	No	NA	Comment
Designs utilized are appropriate for the indications requested.			X	
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.			X	
Interim analyses (if present) were pre-specified in the protocol and appropriate adjustments in significance level made. DSMB meeting minutes and data are available.			X	
Appropriate references for novel statistical methodology (if present) are included.			X	
Safety data organized to permit analyses across clinical trials in the NDA/BLA.			X	
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.			X	

Information requests for the Applicant: None at this time.

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