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

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number:	204426
Drug Name:	(b) (4)
Indication(s):	Prevention of Pregnancy
Applicant:	Warner Chilcott
Date(s):	Submission Date: 6/21/2012
	PDUFA Due Date: 4/21/2012
Review Priority:	Standard
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Kate Dwyer, Ph.D.
Concurring Reviewers:	Mahboob Sobhan, Ph.D.
Medical Division:	Division of Reproductive and Urologic Drug Products
Clinical Team:	Daniel Davis, M.D., Medical Reviewer
	Lisa Soul, M.D., Team Leader
Project Manager:	Pamela K. Lucarelli

Keywords: NDA review, clinical studies

BACKGROUND

This submission is a 505(b)(1) in support of [redacted] for the prevention of pregnancy. One bioavailability study (Study PR-00810) was submitted in order to establish that [redacted] capsules are bioequivalent to Loestrin 24 Fe tablets. The efficacy of [redacted] is based on the bioequivalence of [redacted] to the approved reference drug product, Loestrin 24 Fe tablets.

CONCLUSION

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

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/s/

KATE L DWYER
11/27/2012