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:	22-501 / Resubmission
Drug Name:	LO LOESTRIN FE (Norethindrone acetate and Ethinyl Estradiol tablets, and Ferrous Fumarate tablets)
Indication(s):	Prevention of Pregnancy
Applicant:	Warner Chilcott Company, Inc.
Date(s):	Submission Date: 4/21/2010
	PDUFA Due Date: 10/21/2010
Review Priority:	Priority
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:	Ronald Orleans, M.D., Medical Reviewer
	Lisa Soule, M.D., Team Leader
Project Manager:	Karl Stiller

Keywords: Labeling review

BACKGROUND

The Applicant has resubmitted this supplement in response to the Complete Response Letter issued by the Agency on January 26, 2010 regarding several manufacturing deficiencies. This is a labeling review for LO LOESTRIN FE, an oral contraceptive, and no additional clinical trial data was included in this submission. The proposed indication is for the prevention of pregnancy in women who elect to use oral contraceptive.

CONCLUSION

The efficacy (using Pearl Index) result in the label was evaluated and verified by this reviewer in the original statistical review of this NDA. Since no additional efficacy data was included in this resubmission, this reviewer agrees with the final version of the label.

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/s/

KATE L DWYER
10/18/2010
re-check in as general review.

MAHBOOB SOBHAN
10/18/2010