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
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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