CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204426Orig1s000

STATISTICAL REVIEW(S)

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:	WC3042
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 WC3042 for the prevention of pregnancy. One bioavailability study (Study PR-00810) was submitted in order to establish that WC3042 capsules are bioequivalent to Loestrin 24 Fe tablets. The efficacy of WC3042 is based on the bioequivalence of WC3042 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

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 20-4426 **Applicant:** Warner Chilcott **Stamp Date:** 06/26/2012

Drug Name: WC3042 **NDA Type:** Standard

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

	Content Parameter	Yes	No	NA	Comments
1	Index is sufficient to locate necessary reports, tables, data, etc.	X			
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)			X	Only one bioavailability study
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).			X	Only one bioavailability study
4	Data sets in EDR are accessible and do they conform to applicable guidances (e.g., existence of define.pdf file for data sets).	X			

IS THE STATISTICAL SECTION OF THE APPLICATION FILEABLE? ___Yes_____

If the NDA/BLA is not fileable from the statistical perspective, state the reasons and provide comments to be sent to the Applicant.

Please identify and list any potential review issues to be forwarded to the Applicant for the 74-day letter.

Content Parameter (possible review concerns for 74-day letter)	Yes	No	NA	Comment
Designs utilized are appropriate for the indications requested.			X	No phase 3 study
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.			X	No phase 3 study
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	No phase 3 study
Appropriate references for novel statistical methodology (if present) are included.			X	No phase 3 study
Safety data organized to permit analyses across clinical trials in the NDA/BLA.			X	No phase 3 study
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.			X	No phase 3 study

Kate Dwyer, Ph.D. 8/15/12

Reviewing Statistician Date

Mahboob Sobhan, Ph.D. 8/15/12

Supervisor/Team Leader Date

File name: 5_Statistics Filing Checklist for a New NDA_BLA110207

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/s/

KATE L DWYER
08/15/2012

MAHBOOB SOBHAN
08/21/2012