CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203752Orig1s000

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#:	203752/N0000
Drug Name:	Minivelle (estradiol transdermal system)
Indication(s):	Moderate to Severe Vasomotor Symptoms associated with Menopause
Applicant:	Noven Pharmaceuticals Inc.
Date(s):	Submission Date: 12/29/2011 PDUFA Due Date: 10/29/2011
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 Reproductive and Urological Drug Products
Clinical Team:	Phill H. Price, MD., Clinical Reviewer Shelley R. Slaughter, MD., Clinical Team Leader
Project Manager:	Samantha S. Bell

Keywords: NDA review, Bioequivalent

BACKGROUND

This submission is a 505(b)(1) NDA application in support of Minivelle for the treatment of moderate to severe vasomotor symptoms associated with menopause. The sponsor, Noven Pharmaceuticals Inc, has the right of reference to Novartis's Vivelle and Vivelle-Dot approved by the Agency under NDA 20-323 and NDA 20-538, respectively. (b) (4)

According to the meeting minutes dated Oct. 5, 2007 under IND 76,647, the sponsor needed to show in vivo bioequivalent (BE) comparing the highest strength of Minivelle and Vivelle.

CONCLUSION

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

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/s/

XIN FANG
09/19/2012

MAHBOOB SOBHAN
09/21/2012

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 203-752/0000 **Applicant:** Noven Pharmaceuticals Inc. **Stamp Date:** 12/29/2011

Drug Name: (b) (4) **NDA/BLA Type:** Original/Standard **Indication:** Moderate to Severe Vasomotor Symptoms associated with Menopause

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	Efficacy and safety are referred to approved Novartis's Vivelle and Vivelle-Dot.
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: No information is requested at this time.

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