

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204308Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 204-308

Applicant: Silvergate

Stamp Date: August 10, 2012

Drug Name: ENALAPED

NDA/BLA 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	The sponsor is relying on the efficacy for the previously approved enalapril (Vasotec®)
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).	x			
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 ___

Note: This is a 505(b)(2) NDA submission. The application relies on the efficacy for the previously approved drug Vasotec. The clinical sections of this application are supported by a comparative bioavailability study. It was decided at the filing meeting that no statistical review is needed for this application.

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 patient-level data are available for the two published pediatric studies
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.			x	Only two publication available, no detailed protocol or SAP
Interim analyses (if present) were pre-specified in the protocol and appropriate adjustments in significance level made. DSMB meeting minutes and data are			x	Only two publication available

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available.				
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	

Reviewing Statistician Date

Supervisor/Team Leader Date

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JIALU ZHANG
09/11/2012

HSIEN MING J HUNG
09/12/2012