

CENTER FOR DRUG EVALUATION AND
RESEARCH

APPLICATION NUMBER:

203791Orig1s000

STATISTICAL REVIEW(S)

Please refer to the Medical Review section of this Approval Package for Additional Statistical Reviews.

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 203,791

**Applicant: Regulatory
Compliance Initiative for
BioAlliance Pharma.**

Stamp Date: Mar. 12, 2012

Drug Name: Sitavig (acyclovir)

NDA/BLA Type: NDA

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.	Y			
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)	Y			
3	Safety and efficacy were investigated for gender, racial, and geriatric subgroups investigated (if applicable).	Y			Subgroup analyses for Efficacy results were presented in ISE section 2.7.3
4	Data sets in EDR are accessible and do they conform to applicable guidances (e.g., existence of define.pdf file for data sets).	Y			

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.	Y			
Endpoints and methods of analysis are specified in the protocols/statistical analysis plans.	Y			
Interim analyses (if present) were pre-specified in the protocol and appropriate adjustments in significance level made. DSMB meeting minutes and data are available.			NA	There is no interim analysis
Appropriate references for novel statistical methodology (if present) are included.			NA	
Safety data organized to permit analyses across clinical trials in the NDA/BLA.			NA	ISS datasets not available.
Investigation of effect of dropouts on statistical analyses as described by applicant appears adequate.	Y			

File name: 5_Statistics Filing Checklist for a New NDA 203,791

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Comments to be converted to the sponsor on April 23, 2012

1. Please submit the executable SAS programs used to generate analysis datasets from SDTM datasets for study BA2005/21/02;

To response this request, the sponsor submitted the SAS programs on April 25, 2012.

<u>Wen Zeng</u>	<u>April. 27, 2012</u>
Reviewing Statistician (Wen Zeng)	Date

<u>Greg Soon</u>	<u>April. 27, 2012</u>
Supervisor/Team Leader (Greg Soon, Statistical 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/

WEN ZENG
04/27/2012

GUOXING SOON
05/16/2012