

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204640Orig1s000

STATISTICAL REVIEW(S)

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 204640 Applicant: JHP Pharmaceuticals Stamp Date: 8/2/2013

Drug Name: Adrenaline 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	No Clinical Studies
2	ISS, ISE, and complete study reports are available (including original protocols, subsequent amendments, etc.)			x	
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

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 Clinical Studies
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	

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Robert Abugov, Ph.D.

9/4/2013

Reviewing Statistician

Date

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

/s/

ROBERT ABUGOV
09/10/2013

JOAN K BUENCONSEJO
09/12/2013
I concur