CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-556Orig1s000

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/BLA Serial Number:	22556
Drug Name:	Carbinoxamine ER Oral Suspension
Indication(s):	Seasonal & perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, urticaria and angioedema, allergic and anaphylactic reactions
Applicant:	Tris Pharmaceuticals
Date(s):	Received: 12-08-2010; PDUFA: 10-08-2011
Review Priority:	S
Biometrics Division:	Division of Biometrics 2
Statistical Reviewer:	Joan Buenconsejo, PhD
Medical Division:	Division of Pulmonary, Allergy and Rheumatology Products
Clinical Team:	Peter Starke, MD
Project Manager:	Miranda Raggio

Keywords: 505b2

1. EXECUTIVE SUMMARY

This is a 505(b)(2) application. The Applicant, Tris Pharmaceutical Inc, submitted this application to support Carbinoxamine extended release oral suspension for the symptomatic treatment of seasonal & perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, urticaria and angioedema, allergic and anaphylactic reactions in patients 17 years of age and older.

Efficacy studies were not conducted with Carbinoxamine Extended Release Oral Suspension. Instead it was based on demonstration of bioavailability and bioequivalence studies. Please refer to Dr. Ping Ji's review and Dr. Peter Starke's review regarding the adequacy of the program.

Because the current submission includes no trials assessing clinical efficacy, Biometrics has no comments.

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/s/

JOAN K BUENCONSEJO
08/02/2011

STATISTICS FILING CHECKLIST FOR A NEW NDA/BLA

NDA Number: 22556 **Applicant:** Tris Pharma **Stamp Date:** 12/08/2010

Drug Name: Carbinoxamine **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.			X	
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_____

NOTE FROM REVIEWER: This is a 505b2 application. The applicant did not conduct clinical study. Therefore, there will be no formal statistics review 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	
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	

Joan Buenconsejo 02-06-11

Reviewing Statistician Date

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/s/

JOAN K BUENCONSEJO
02/07/2011