CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022439Orig1s000

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:	NDAs 22439 and 22442
Drug Name:	[redacted] (b) (4) and Rezira (oral)
Indication(s):	cough suppressant, antihistamine, decongestant
Applicant:	Cypress Pharmaceuticals
Date(s):	Received: 12-08-2010; PDUFA: 06-08-2011
Review Priority:	P
Biometrics Division:	Division of Biometrics 2
Statistical Reviewer:	Joan Buenconsejo, PhD
Medical Division:	Division of Pulmonary, Allergy and Rheumatology Products
Clinical Team:	Xu Wang, MD
	Anthony Durmowicz, MD
Project Manager:	Philantha Bowen

Keywords: 505b2

1. EXECUTIVE SUMMARY

This is a 505(b)(2) application. The Applicant, Cypress Pharmaceutical Inc, submitted this application to support two immediate release oral solution combination products, NDA 22-439 [redacted] (b) (4) (containing hydrocodone bitartrate, chlorpheniramine maleate, and pseudoephedrine hydrochloride 5, 4, and 60 mg, respectively, per 5 ml) and NDA 22-442 Rezira (containing hydrocodone bitartrate and pseudoephedrine hydrochloride 5 and 60 mg, respectively, per 5 ml).

This is a clinical pharmacology program. Please refer to Dr. Elizabeth Shang's review and Dr. Xu Wang'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
04/21/2011