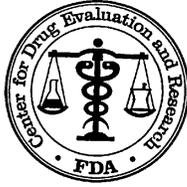


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22442Orig1s000

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:**

NDA's 22439 and 22442

Drug Name:

(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 (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