CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209139Orig1s000

STATISTICAL REVIEW(S)

Statistical Review and Evaluation

NDA#: 209139 **Sn #:** 000 **Date Received:** 12/30/2016
Drug Name: PREXXARTANTM (valsartan) Oral Solution, 4 mg/mL
Indication: Treatment of Hypertension, Heart Failure (NYHA class II-IV), and Reduction of Cardiovascular Mortality in Clinically Stable Patients with Left Ventricular Failure or Left Ventricular Dysfunction Following Myocardial Infarction
Statistical Reviewer: Ququan Liu **Medical Reviewer:** Kimberly Smith
Sponsor: CARMEL Biosciences

This is a 505(b)(2) NDA submission. The submission relies on:

1) The FDA's previous finding of safety and effectiveness for the listed drug Diovan® (valsartan) tablets (320 mg). Novartis Pharmaceuticals Corporation received original approval for Diovan® (valsartan) tablets under NDA 021283 on July 18, 2001.
2) Two studies conducted by CARMEL Biosciences: a comparative bioavailability study (055-BE-2013) and a PK study (059-PK-2014).

In the 45-day filling meeting, it's decided no statistical review is needed for this submission, because there is no new clinical study conducted.

Cc:Hung
Liu
Patricians

Date: 02/23/2017
This review consists of 1 page of text
209139_000.doc

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

/s/

QUQUAN LIU
02/23/2017