CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201739Orig1s000

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/Serial Number:	NDA201739/S-00
Drug Name:	Epinephrine Auto-Injector 0.15mg and Epinephrine Auto-Injector 0.3mg
Indication(s):	Emergency treatment of allergic reactions
Applicant:	Intellijject
Date(s):	9/29/2010
Review Priority:	10-months
PDUFA	7/29/2011

Biometrics Division:	Division of Biometrics II/Office of Biostatistics
Statistical Reviewer:	Feng Zhou, M.S.
Concurring Reviewers:	Joan Buenconsejo, Ph.D., Team Leader Thomas Permutt, Ph.D., Division Director
Medical Division:	Division of Pulmonary and Allergy Products
Clinical Team:	Brian Porter, M.D. (Medical Reviewer) Susan Limb, M.D. (Medical Team Leader) Badrul Chowdhury, M.D., Ph.D. (Medical Division Director)
Project Manager:	Ramsey, Angela

Keywords: Clinical Studies, bioavailability

1. EXECUTIVE SUMMARY

1.1 Conclusions and Recommendations

Pursuant to 505(b)(2) of the Food, Drug and Cosmetic Act and in accordance with 21 C.F.R. Part 314, the sponsor, Intellijject Inc., submitted NDA 201739 for an epinephrine auto-injector (EAI) provisionally named [redacted] (b) (4) (0.15 mg and 0.3 mg), delivered as an intramuscular injection, for the emergency treatment of allergic reactions (Type 1). Selection of the appropriate dosage strength is determined according to patient body weight (15-30 kg (0.15 mg dose) and ≥ 30 kg (0.3 mg dose)).

This application references the EpiPen® and EpiPen Jr® epinephrine auto-injector (NDA 19-430; Meridian Medical Technologies; approved December 22, 1987) as the reference listed combination drug device.

EAI is being developed with the goal of decreased dosing errors by virtue of a unique self-actuated electronic injector device with interactive voice and visual prompts. The development program for EAI was based on three simulated clinical use studies to evaluate human factors in which no active drug was injected into human subjects (INT0801, INT0803, INT-FE-0901) and a single comparative bioavailability trial (INT0802), for which the complete study reports have been provided in support of a proposed indication for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients 15-30 kg (0.15 mg dose) and ≥ 30 kg (0.3 mg dose). The pivotal bioavailability trial was designed as a randomized, single-blind, two-treatment (EAI versus EpiPen), three-period (1 for EAI and 2 for EpiPen), three sequence (randomized 1:1:1 to EAI-EpiPen-EpiPen; EpiPen-EAI-EpiPen; EpiPen-EpiPen-EAI) cross-over study to evaluate potential bioequivalence of a single dose of injectable epinephrine 0.3 mg delivered by one of two forms of auto-injectors to healthy adults aged 18-45 years.

The Clinical Pharmacology reviewer Dr. Liang Zhao conducted a thorough review on study INT0802. Therefore, there is no need for statistic review.

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/s/

FENG ZHOU
03/24/2011

JOAN K BUENCONSEJO
03/25/2011
I concur with Ms. Feng Zhou's review.