CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209661Orig1s000

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

SUPPLEMENT REVIEW

NDA Serial Number:	21876 / S-10
Drug Name:	Diclegis® (20 mg doxylamine succinate and 20 mg pyridoxine hydrochloride) (b) (4) Tablets
Indication(s):	Treatment of nausea and vomiting of pregnancy in patients who do not respond to conservative management
Applicant:	Duchesnay, Inc.
Date(s):	Submission Date: 10/07/2015
	PDUFA Due Date: 04/07/2016
Review Priority:	Standard
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Kate Dwyer, Ph.D.
Concurring Reviewer:	Mahboob Sobhan, Ph.D., Team Leader
Medical Division:	Division of Reproductive and Urologic Drug Products
Clinical Team:	Theresa Van Der Vlugt, M.D., Medical Reviewer
	Shelley R. Slaughter, M.D., Team Leader
Project Manager:	George Lyght

Keywords: NDA review

The Applicant, Duchesnay Inc. submitted the Supplemental NDA for a reformulated 20 mg doxylamine succinate and 20 mg pyridoxine hydrochloride [redacted] (b) (4) tablet containing an immediate release portion in addition to the delayed release core for the same indication.

There are no new clinical data submitted to this Supplement, thus no statistical review is necessary.

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/s/

KATE L DWYER
02/29/2016