CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212909Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

FDA CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY
10903 NEW HAMPSHIRE AVENUE, BLDG 51, SILVER SPRING, MARYLAND 20993

Memorandum

NDA or BLA Number	212909
Link to EDR	\\Cdsesub1\evsprod\NDA212909
Submission Date	December 21, 2018
Submission Type	Standard
Brand Name	BiorPHEN and Phenylephrine Hydrochloride Injection
Generic Name	Phenylephrine hydrochloride Injection USP, 0.1 mg/mL and Phenylephrine hydrochloride Injection USP (b) (4) (b) (4) for Intravenous Administration
Dosage Form and Strength	Solutions; 0.1 mg/mL (b) (4)
Route of Administration	Intravenous
Proposed Indication	For the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.
Applicant	Sintetica S.A.
Associated IND	NA
OCP Review Team	Wei Qiu, PhD., Yun Xu, MD, PhD.

Recommendation:

The Office of Clinical Pharmacology/Division of Clinical Pharmacology 2 (OCP/DCP-2) has reviewed NDA 212909 submitted on December 21, 2018 and finds it acceptable. There is no difference in clinical pharmacology related labeling sections (i.e., 7 DRUG INTERACTIONS, 8.6 Hepatic Impairment, 8.7 Renal Impairment, 12.3 Pharmacokinetics) between the proposed products (Phenylephrine hydrochloride Injection USP, 0.1 mg/mL (b) (4) and the list drug product VAZCULEP (phenylephrine hydrochloride) Injection, (b) (4) (b) (4)

Sintetica S.A. submitted an 505(b)(2) NDA 212909 for Phenylephrine hydrochloride Injection USP, 0.1 mg/mL (b) (4) for the treatment of clinically important

hypotension resulting primarily from vasodilation in the setting of anesthesia on December 21, 2018. The sponsor seeks approval by making reference to the Agency's previous finding of safety and efficacy of their identified list drug product, Vazculep® (phenylephrine hydrochloride Injection, 10 mg/mL; NDA 204300). No clinical pharmacology study has been submitted for review. Instead, the sponsor requested a biowaiver in their NDA submission. ONDQA/Biopharm review stated "*The Applicant provided adequate justification for the differences in the inactive ingredients and provided comparative physiochemical property data between the proposed and listed drug products. Consistent with 21 CFR 320.24 (b)(6), the information supporting the* ***biobridge*** *of the Applicant's proposed drug product to the listed drug is adequate. Thus, an additional in vivo bioequivalence (BE) bridging study is not needed. Therefore, NDA 212909 for Phenylephrine Hydrochloride Injection USP, 0.1 mg/ml* (b) (4) *is* ***recommended for approval***" (see ONDQA/Biopharm review for more details).

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/s/

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