CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210997Orig1s000
210997Orig2s000

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

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

Memorandum

DATE	June 14, 2018
NDA	210997
PRODUCT	Glycopyrrolate Injection, USP, 0.2 mg/mL vial (0.2 mg/1 mL and 0.4 mg/2 mL)
SUBJECT CLINICAL PHARMACOLOGY REVIEWER	Wei Qiu, Ph.D.
CLINICAL PHARMACOLOGY TEAM LEADER	Yun Xu, Ph.D.

Recommendation:

The Office of Clinical Pharmacology/Division of Clinical Pharmacology 2 (OCP/DCP-2) has reviewed NDA 210997 submitted on September 5, 2017 and finds it acceptable if a mutual agreement is reached on the labeling language. As of today (6/14/18), the labeling negotiation is still ongoing.

Exela Pharma Sciences submitted an 505(b)(2) NDA 210997 for Glycopyrrolate Injection, USP, 0.2 mg/mL for use in anesthesia and peptic ulcers on September 5, 2017. The sponsor seeks approval by making reference to the Agency's previous finding of safety and efficacy of their identified list drug product, Robinul Injection (NDA 017558). No clinical pharmacology study has been submitted for review. Instead, the sponsor requested a biowaiver in their NDA submission and the biowaiver is granted by the ONDQA/Biopharm review team (see Biopharm review for more details).

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/s/

WEI QIU
06/14/2018

YUN XU
06/14/2018