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APPLICATION NUMBER:

215212Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

Office of Clinical Pharmacology Memo

NDA Number	215212
Submission Date	11/16/2020
Submission Type	505 (b)(2); standard
Brand Name, Drug, Dosage Form and Strength	Meropenem for injection, (b) (4) 2 gram/vial
Route of Administration	Intravenous injection
Proposed Indication	Treatment of bacterial meningitis (pediatric patients 3 months of age and older only)
Applicant	HQ Specialty Pharma Corporation
OCP Division	DIDP
OND Division	DAI
OCP Review Team	Xiaohui (Tracey) Wei, Ph.D.: Clinical Pharmacology Reviewer Seong H Jang, Ph.D.: Clinical Pharmacology Team Leader
OCP Final Signatory	Seong H Jang, Ph.D.

1. Executive Summary

HQ Specialty Pharma Corporation submitted a 505(b)(2) NDA for meropenem for Injection, (b) (4) 2g for the treatment of bacterial meningitis (pediatric patients 3 months and older only) caused by *Haemophilus influenzae*, *Neisseria meningitidis* and penicillin-susceptible isolates of *Streptococcus pneumoniae*.

Meropenem is marketed in the 500 mg/vial and 1 gram/vial dosage strengths as Merrem® under NDA 050706 with the following approved indications:

- Complicated skin and skin structure infections (adult patients and pediatric patients 3 months of age and older only)
- Complicated intra-abdominal infections (adult and pediatric patients)
- Bacterial meningitis (pediatric patients 3 months of age and older only).

The application relies on data concerning safety, efficacy, clinical pharmacology, and nonclinical pharmacology as well as PK and PD studies from Merrem® (NDA 050706) as the reference listed drug (RLD).

The proposed product contains the same ingredients as the RLD MERREM® as well as the same route of administration and dosage form but contains a different strength per vial (2 g/vial). The

same diluents listed for the RLD will also be utilized for reconstitution prior to the administration. The RLD Package Insert indicates up to a 2 gram dose. The 2 g per vial formulation allows for handling of the drug in the higher dosing range with half the number of vials having to be reconstituted with diluent.

No additional clinical studies were conducted for this NDA. The recommended dosage and administration regimen are the same as RLD for the indication of bacterial meningitis. Therefore, it is expected that the proposed Meropenem for Injection will have the same clinical pharmacology profile as the RLD.

2. Recommendations

The Clinical Pharmacology review team recommends approval of this NDA. The Clinical Pharmacology relevant labeling edits are ongoing.

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/s/

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07/26/2021 09:48:38 AM

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