CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202106Orig1s000

SUMMARY REVIEW

Division Director Decisional Memo

Date	(electronic stamp)
From	Sumathi Nambiar MD MPH
Subject	Division Director Decisional Memo
NDA #	202106
Applicant Name	B. Braun Medical Inc.
Date of Submission	October 30, 2014*
PDUFA Goal Date	April 30, 2015
Established (USAN) Name	Meropenem for Injection USP and Sodium Chloride Injection USP in Duplex® Container
Dosage Forms / Strength	500 mg of Meropenem for Injection and 50 mL of Sodium Chloride 1 g of Meropenem for Injection and 50 mL of Sodium Chloride
Proposed Indications	Complicated skin and skin structure infections Complicated intra-abdominal Infections Bacterial meningitis
Recommended Action:	Approval

*Resubmission after Complete Response Action

Material Reviewed/Consulted Action Package including:	**Names of Discipline Reviewers**
Pharmacology Toxicology Review	Amy Ellis PhD
Chemistry Manufacturing and Controls Review	Lin Qi PhD
Biopharmaceutics Review	Elsbeth Chikhale PhD
Cross-Discipline Team Leader Review	Dorota Matecka PhD
Medical Officer Review	Alma Davidson MD
Statistical Review	Margaret Gamalo PhD
Product Quality Review	Vinayak Pawar PhD
Microbiology Review	Kerian Grande Roche PhD
Clinical Pharmacology Review	Ryan Owen PhD
Division of Medication Error Prevention and Analysis	Aleksander Winiarski Pharm D/ Jacqueline Sheppard, Pharm D
Labeling Review/Office of Prescription Drug Promotion (OPDP)	Carrie Newcomer PharmD/ Puja Shah, Pharm D

1.0 Introduction

NDA 202106, Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex® Container was submitted by B. Braun Medical Inc. This NDA was submitted as a 505(b)(2) application and the listed drug is Merrem® I.V. (meropenem for injection), 500 mg/vial and 1 gram/vial (NDA 50706), held by Astra Zeneca Pharmaceuticals. Merrem is approved for the treatment of the following infections:

- Complicated skin and skin structure infections
- Complicated intra-abdominal infections
- Bacterial meningitis

The NDA was originally submitted on September 27, 2013. A complete response letter was issued on July 25, 2014 as the status of the proposed drug product manufacturing facility (Facta Farmaceutici S.p.A., Teramo, Italy) was "Unacceptable". On October 30, 2014, the Applicant submitted a complete response to the CR action.

In the first review cycle, all reviewers besides the CMC reviewer recommended approval. For details, please refer to the reviews and the Cross-Discipline Team Leader review (CDTL) filed during the first review cycle. This memo only covers issues relevant to the resubmission.

2.0 Product Quality

The Chemistry, Manufacturing and Controls (CMC) reviewer for this application is Lin Qi, PhD, and the product quality microbiology reviewer is Vinayak Pawar, PhD.

Dr. Qi, PhD had recommended a non-approval in the first cycle based on an unacceptable status of the drug product manufacturing facility, Facta Farmaceutici S.p.A., in Teramo, Italy and the Overall "Withhold" Recommendation received from the Office of Compliance (for details refer to the review dated June 20, 2014 in DARRTS). The issues with the drug product facility have been resolved satisfactorily and the Overall Manufacturing Inspection Recommendation issued by the Office of Process and Facilities for this NDA is "Acceptable". In addition, as recommended by the Agency, the term (b) (4) was replaced with "Duplex Container" in the currently proposed labeling. Dr. Qi found the labeling to be acceptable and recommends approval of this NDA from the Product Quality perspective.

3.0 Biopharmaceutics

Elsbeth Chikhale, PhD, is the biopharmaceutics reviewer for this application. Dr. Chikhale found the application approvable during the first cycle review. In accordance with

21 CFR 320.22(b) Dr. Chikhale agrees with the request for a biowaiver and continues to recommend approval of the NDA.

4.0 Clinical Microbiology

Kerian Grande Roche, PhD, is the clinical microbiology reviewer for this application. No new clinical microbiology information was submitted in this application. Dr. Grande Roche incorporated her microbiology edits into the Division's final labeling.

5.0 Clinical Efficacy/Safety

Alma Davidson, MD, is the clinical reviewer for this application. No new clinical or statistical information was submitted in this NDA. Recommendations for edits to the labeling have been incorporated. Dr. Davidson recommends approval of the NDA.

6.0 Labeling

Labeling recommendations from Aleksander Winiarski, PharmD, and Jacqueline Sheppard, PharmD, from the Division of Medication Error Prevention and Analysis (DMEPA) have been incorporated in the final version of the labeling. Carrie Newcomer, PharmD, from the Office of Prescription Drug Promotion (OPDP) provided original labeling recommendations which have been incorporated in the labeling. Additionally, Puja Shah, PharmD, from OPDP, reviewed the labeling submitted in the resubmission. The final version of the labeling reflects the team's agreements.

7.0 Recommended Regulatory Action

I agree with the recommendations made by the review team and the cross-discipline team leader that this NDA covered under 505(b)(2) be approved, relying on the Agency's prior findings of safety and effectiveness of the listed drug product, Merrem I.V. (NDA 50706). The deficiency related to the manufacturing site has been resolved and the overall recommendation from the Office of Process and Facilities is acceptable for the drug product manufacturing facility, Facta Farmaceutici S.p.A., Teramo, Italy.

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/s/

SUMATHI NAMBIAR
04/30/2015