

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202106Orig1s000

PHARMACOLOGY REVIEW(S)

Sections 8.1 and 13 of the label are acceptable. The sponsor made the changes requested by the Division on 3/27/15.

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/s/

AMY L ELLIS
04/23/2015

PHARMACOLOGY/TOXICOLOGY REVIEW
NDA 202106
MEROPENEM FOR INJECTION USP in the DUPLEX CONTAINER, 0.5 g and 1 g, with
SODIUM CHLORIDE INJECTION USP DILUENT

DATE: 5/2/14

TO: Maureen Dillon-Parker
Chief Project Manager, DAIP
and
File, NDA 202106

FROM: Amy L. Ellis, Ph.D.
Pharmacologist, DAIP

THROUGH: Wendelyn Schmidt, Ph.D.
Supervisory Pharmacologist, DAIP

RE: Pharmacology/Toxicology Review of NDA 202106, Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container, 0.5 g and 1 g

This NDA is for a sterile dual chamber bag (Duplex® container) that contains Meropenem for Injection USP powder in one compartment and the diluent Sodium Chloride Injection USP in the other. Pressure is applied to the diluent chamber to break the seal between it and the chamber containing the powder, reconstituting the product for administration. For each gram of meropenem, (b) (4) mg of sodium carbonate is present (b) (4). The bags will contain (b) (4) ml of the diluent when initially released for sale (to maintain the USP volume of 50 ml over the shelf life of the product). Sodium Chloride USP is one of the diluents recommended on the Merrem® label. The sponsor, B. Braun Medical Inc. (Allentown, PA), is requesting approval of the current product for most of the same indications as the reference listed drug Merrem® to which it is bioequivalent. The bacterial meningitis indication is not being requested because the product cannot be used in pediatric patients who are too small to receive a full 0.5 g dose of meropenem. The Duplex® container to be used for Meropenem for Injection USP and Sodium Chloride Injection USP is identical to the container used by the sponsor for several cephalosporin products that they market in the U.S. (e.g., cefazolin, cefoxitin, ceftazidime, among others) with Dextrose Injection USP as diluent.

NDA 202106 does not require a pharmacology/toxicology review. The sponsor did not conduct any additional nonclinical toxicology studies to support the current NDA. The Division agreed that nonclinical studies would not be necessary as long as there are no impurities or degradation products in Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container that exceed ICH qualification threshold levels or the levels in comparable marketed products such as Merrem®. Thus far, it appears that there are no impurities or degradation products in the current product that require qualification via nonclinical testing,

according to the Chemistry Reviewer. The sponsor has requested that the Agency rely on its findings of safety and effectiveness for the approved product Merrem® to support this NDA for the current product, Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container, as permitted under section 505(b)(2) of the FD&C Act.

The pharmacologist has no objection to the approval of NDA 202106 for Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container, provided that the Chemistry Reviewer agrees with the sponsor's assessment that the product contains no impurities or degradation products that need to be qualified via nonclinical testing. The label for this product should, in general, be consistent with the label for Merrem® (NDA 050706). The label for Meropenem for Injection USP and Sodium Chloride Injection USP in the Duplex Container was written in PLR format, so a few editorial changes were made to Sections 8.1 and 13 for clarity. None were scientifically substantive.

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/s/

AMY L ELLIS
05/06/2014

WENDELYN J SCHMIDT
05/22/2014