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*APPLICATION NUMBER:*

**050823Orig1s000**

**PHARMACOLOGY REVIEW(S)**

Memo to the Division File

NDA 50-823, submitted to the EDR on 8/12/10

B. Braun's ceftazidime for injection and dextrose injection USP in a duplex container

To: Chris Davi, Project Manager, DAIOP

From: Wendelyn Schmidt, Pharmacology/Toxicology Supervisor, DAIOP

Through: Amy Ellis, Pharmacology/Toxicology Secondary Reviewer

Date: September 29, 2010

Background:

The sponsor, B. Braun, has submitted a NDA for a new packaging system (duplex container system) for intravenous ceftazidime and dextrose. The sponsor states that the formulation is identical to ceftazidime (Fortaz) approved under NDA 50578 and is thus a 505(b)(2) application. The packaging will contain 1 or 2 g of ceftazidime and 118 mg/g of sodium carbonate packaged with dextrose injection USP. No new pharmacology or toxicology information was submitted, or necessary in support of this new format. At this time, no new impurities have been identified. The package insert labeling is identical to the GlaxoSmithKline label except for the identification of the sponsor/manufacturer. No labeling changes are needed.

Recommendation: There are no pharmacology/toxicology objections to this approval of ceftazidime in the duplex container.

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/s/

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WENDELYN J SCHMIDT  
09/30/2010

AMY L ELLIS  
09/30/2010