

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

050823Orig1s000

Trade Name: CEFTAZIDIME FOR INJECTION USP AND DEXTROSE INJECTION USP IN DUPLEX® CONTAINER

Generic Name: CEFTAZIDIME

Sponsor: B. BRAUN MEDICAL INC.

Approval Date: 06/13/2011

Indications: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ceftazidime for Injection USP and Dextrose Injection USP and other antibacterial drugs, Ceftazidime for Injection USP and Dextrose Injection USP should be used only to treat infections that are proven or strongly suspected to be caused by bacteria.

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APPROVAL LETTER



NDA 50-823

NDA APPROVAL

B. Braun Medical, Inc.
Attention: Rebecca Stolarick
Director of Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Stolarick:

Please refer to your New Drug Application (NDA) dated August 12, 2010, received August 13, 2010, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ceftazidime for Injection, USP and Dextrose Injection, USP in the Duplex Container.

We also acknowledge receipt of your amendments dated September 13, and October 13, 2010, February 18, March 29, April 27, May 26 and 27 and June 3, 2011.

This new drug application provides for a new packaging configuration of Ceftazidime, in the Duplex packaging system.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

IMMEDIATE CONTAINER LABELS

We acknowledge your June 3, 2011, submission containing final printed drug chamber and immediate container labels. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROPRIETARY NAME

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Immediate Container & Drug Chamber Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KATHERINE A LAESSIG
06/13/2011