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RESEARCH**

APPLICATION NUMBER:
50-821

OTHER ACTION LETTER(S)



NDA 50-821

COMPLETE RESPONSE

B. Braun Medical, Inc.
Attention: Susan Olinger, J. D.
Corporate Vice President, Regulatory Affairs
901 Marcon Boulevard
Allentown, PA 18109

Dear Ms. Olinger:

Please refer to your new drug application (NDA) dated September 25, 2008, received September 25, 2008, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cefepime for Injection, USP and Dextrose Injection, USP in the Duplex[®] Container, 1g and 2g.

We also acknowledge receipt of your amendments dated November 21 and December 5, 2008, and January 29, February 18 and 25, and April 8, 2009.

We have completed the review of your application, as amended, and have determined that we cannot approve this application in its present form. We have described below our reasons for this action and where possible, our recommendations to address these issues.

PRODUCT QUALITY

1. FDA inspection of the [REDACTED] (b) (4) [REDACTED] (b) (4) revealed significant deviations from current Good Manufacturing Practice (cGMP) regulations. A satisfactory resolution of these deficiencies is required before this application can be approved.
2. DMF [REDACTED] (b) (4) has been found inadequate at this time to support NDA 50-821. We have been in communication with the DMF holder to provide additional information.

LABELING

We reserve comment on the proposed labeling until the application is otherwise adequate. If you revise labeling, your response must include updated content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>.

SAFETY UPDATE

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all nonclinical and clinical studies/trials of the drug under consideration regardless of indication, dosage form, or dose level.

OTHER

Within one year after the date of this letter, you are required to resubmit or take one of the other actions available under 21 CFR 314.110. If you do not take one of these actions, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with us to discuss what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the FDA Guidance for Industry *Formal Meetings With APPLICANTs and Applicants for PDUFA Products*, February, 2000 (<http://www.fda.gov/cder/guidance/2125fnl.htm>).

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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 and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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/s/

Kathrine Laessig
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