

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-817

OTHER ACTION LETTER(s)



NDA 50-817

Baxter Healthcare Corporation
Attention: Vicki L. Drews
Associate Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Ms. Drews:

Please refer to your new drug application (NDA) dated February 28, 2007, received March 1, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Cefepime Injection in GALAXY Container (PL 2040 Plastic), 1g/50 mL and 2g/100 mL.

We acknowledge receipt of your submissions dated March 19, May 7, July 13, and November 30, 2007.

We completed our review of this application, as amended, and it is approvable. Before the application may be approved, however, it will be necessary for you to:

- Identify the equipment to be used for _____ processing of the drug product and its location within the manufacturing facility. **b(4)**
- Provide the methodology and acceptance criteria for filter integrity testing.

The microbiology deficiencies identified during the review of DMF _____ should be addressed. **b(4)**

In addition, it will be necessary for you to submit revised draft final printed labeling (FPL) identical to the enclosed label. Submit carton and container labels containing recommendations consistent with the letter issued on August 24, 2007.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Infective and Ophthalmology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of the other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Anti-Infective and Ophthalmology Products to discuss what steps need to be taken before the application may be approved.

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

If you have any questions, call Kyong Hyon, Regulatory Project Manager, at (301) 796-0734

Sincerely,

{See appended electronic signature page}

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

27 Page(s) Withheld

 Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

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

/s/

Kathrine Laessig
12/21/2007 03:40:09 PM