DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200327/S-005

SUPPLEMENT APPROVAL

Cerexa, Inc.
Attention: Kristina Haeckl, RAC
Executive Director, Regulatory Affairs
2100 Franklin St., Suite 900
Oakland, CA 94612

Dear Ms. Haeckl:

Please refer to your Supplemental New Drug Application (sNDA) dated October 21, 2011, received October 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Teflaro (ceftaroline fosamil) for Injection.

The January 27, 2012, submission constituted a complete response to our January 5, 2012, action letter.

This "Changes Being Effected" supplemental new drug application provides for the following:

- Relocate established (ceftaroline fosamil for injection) name under proprietary (Teflaro) name and increase font size
- Increase font size of proprietary name to be consistent with revised font size for established name
- Replace statements in front display panel to allow room for larger font size of established and proprietary name

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

We acknowledge your January 27, 2012, submission containing final printed container labels.

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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

John J. Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Container Labeling

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

/s/

JOHN J FARLEY
05/22/2012