DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 200327/S-010

SUPPLEMENT APPROVAL

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

Dear Ms Haeckl:

Please refer to your Supplemental New Drug Application (sNDA) dated March 29, 2013, received March 29, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Teflaro ® (ceftaroline fosamil) for Injection

This "Prior Approval" supplemental new drug application provides for:

1. Change the drug products' storage conditions from "Refrigerated, 5°C; with excursions permitted to 2 to 8°C (36°F to 46°F)" to "Controlled room temperature storage, 25°C; with excursions permitted to 15-30°C (59°F to 86°F), USP".
2. Add a new specified impurity (b) (4) as a Related Substance in the drug product specifications, with a proposed limit of NMT (b) (4) % specified.
3. Assign 24-months of shelf-life for the drug products at controlled room temperature, USP conditions.
4. Labeling changes associated with the above changes

We have completed our review of this supplemental new drug application. This supplement is approved.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, immediate container labels, and carton labels), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 200327/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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 Althea Cuff, Regulatory Health Project Manager, at (301) 796-4061.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, Ph.D.
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and 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/

DAVID B LEWIS
07/29/2013
Approval; signing for T. Oliver