DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-685/S-012
NDA 50-686/S-015

SUPPLEMENT APPROVAL

Pernix Therapeutics, LLC
Attention: Beth DeVille
Vice President
208 W. East Bank Drive
Gonzales, LA 70737

Dear Ms. DeVille:

Please refer to your supplemental new drug applications (sNDA's) dated March 31, 2009, received April 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CEDAX (ceftibuten capsules)[NDA 50-685] and CEDAX (ceftibuten oral suspension) [NDA 50-686].

We also acknowledge receipt of your correspondences dated March 3, and August 22, 2008.

These 'Prior Approval' supplemental new drug applications provide for a response to our letter of January 6, 2008, requesting updates to the *in vitro* susceptibility test interpretive criteria (breakpoints) and the quality control parameters for *in vitro* susceptibility testing listed in the package insert as applicable.

We have completed our review of these applications and find the data submitted to support changing the Quality Control (QC) parameter for *Haemophilus Influenzae* ATCC 49247 from 29-35 mm to 28-34 mm in the **CLINICAL PHARMACOLOGY, *Microbiology Subsection*** acceptable. Therefore, these supplements are approved, effective on the date of this letter.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the labeling submitted March 31, 2009, and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in these supplemental applications.

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 regarding these specific supplements, call Maureen Dillon-Parker, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

WILEY A CHAMBERS
11/04/2010