DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-611/S-031 **SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Richard Leber
Manager. Global Pharmaceutical Regulatory Affairs
Dept. PA76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Leber:

Please refer to your supplemental new drug application (sNDA) dated July 31, 2008, received August 01, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PCE (erythromycin) Dispertab Tablets.

We also acknowledge receipt of your correspondence dated March 14, 2008.

This 'Prior Approval' supplemental new drug application provides 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 this application and find the current literature supports that no changes are required to the *Staphylococcus spp. in vitro* susceptibility test interpretive criteria or quality control parameters for both broth dilution testing (MIC) and disk diffusion criteria at this time. We also agree with the addition of *Streptococcus pneumoniae* and *Streptococcus spp* to the package insert in both the MIC and disk diffusion *in vitro* susceptibility test interpretive criteria and the *in vitro* susceptibility test quality control parameters. Therefore, this supplement is approved, effective on the date of this letter.

We request that you update the Clinical Laboratory Standards Institute (CLSI) references in the package insert to reflect the most recent CLSI publications at the next printing of the labeling.

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 July 31, 2008, 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 this NDA, 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 this supplemental application.

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