Dear Ms. Kirzecky:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

<table>
<thead>
<tr>
<th>NDA #</th>
<th>Supplement #</th>
<th>Submission Date:</th>
<th>Name of Drug Products:</th>
</tr>
</thead>
<tbody>
<tr>
<td>21-130</td>
<td>023</td>
<td>June 30, 2010</td>
<td>Zyvox (linezolid) Tablets</td>
</tr>
<tr>
<td></td>
<td>024</td>
<td>October 27, 2010</td>
<td>Zyvox (linezolid) Tablets</td>
</tr>
<tr>
<td>21-131</td>
<td>021</td>
<td>June 30, 2010</td>
<td>Zyvox (linezolid) IV Injection</td>
</tr>
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<td>022</td>
<td>October 27, 2010</td>
<td>Zyvox (linezolid) IV Injection</td>
</tr>
<tr>
<td>21-132</td>
<td>022</td>
<td>June 30, 2010</td>
<td>Zyvox (linezolid) for Oral Suspension</td>
</tr>
<tr>
<td></td>
<td>023</td>
<td>October 27, 2010</td>
<td>Zyvox (linezolid) for Oral Suspension</td>
</tr>
</tbody>
</table>

We acknowledge receipt of your amendments, dated December 21, 2012, which constituted a complete response to our October 17, 2011, action letter.

These “Prior Approval” supplemental new drug applications provide for the following:

**June 30, 2010:**

- Draft labeling to comply with the FDA’s final Physician Labeling Rule (PLR) on the content and format of labeling for human prescription drug and biological products.

**October 27, 2010:**

- Revisions to the **CLINICAL PHARMACOLOGY, Pharmacokinetics, Specific Populations** and Drug Interactions subsections.
We have completed our review of these applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at [http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm). Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.


The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

**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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE: Approved Labeling

Reference ID: 3303311
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
05/03/2013