DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-130/S-023 & S-024
NDA 21-131/S-021 & S-022
NDA 21-132/S-022 & S-023

SUPPLEMENT APPROVALS

Pfizer Global Pharmaceuticals
Attention: Nadia D. Kirzecky
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

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:

NDA #	Supplement #	Submission Date:	Name of Drug Products:
21-130	023	June 30, 2010	Zyvox (linezolid) Tablets
	024	October 27, 2010	Zyvox (linezolid) Tablets
21-131	021	June 30, 2010	Zyvox (linezolid) IV Injection
	022	October 27, 2010	Zyvox (linezolid) IV Injection
21-132	022	June 30, 2010	Zyvox (linezolid) for Oral Suspension
	023	October 27, 2010	Zyvox (linezolid) for Oral Suspension

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. 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.

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 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

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