DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-130/S-010
NDA 21-131/S-011
NDA 21-132/S-010

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

Dear Dr. Kirzecky:

Please refer to your supplemental new drug applications for Zyvox (linezolid) Tablets (NDA 21-130/S-010), Zyvox (linezolid) IV Injection (NDA 21-131/S-011), and Zyvox (linezolid) Oral Suspension (NDA 21-132/S-010).

We acknowledge receipt of your submissions dated October 11, 2005.

These supplemental new drug applications provide for the changes of the language in the PRECAUTIONS section, General subsection of the label.

We 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 dated October 11, 2005. In addition, correct the spelling of Serontonin Syndrome to Serotonin Syndrome in the PRECAUTIONS section, General subsection of the label.

The final printed labeling (FPL) must include the revision indicated. This revision is terms of the approval of these applications. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 21-130/S-010, NDA 21-131/S-011, and NDA 21-132/S-010**." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Kyong Hyon, Regulatory Project Manager, at (301) 796-0734.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
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/

Janice Soreth
11/2/2005 03:58:15 PM