



NDA 21-130/S-006
NDA 21-131/S-007
NDA 21-132/S-006

Pharmacia & Upjohn Company
c/o Pfizer Inc.
Attention: Roberta A. Krieger
Manager
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Ms. Krieger:

Please refer to your supplemental new drug applications dated December 19, 2003, received December 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyvox™ (linezolid) Tablets (NDA 21-130), Zyvox™ (linezolid) IV Injection (NDA 21-131) and Zyvox™ (linezolid) Oral Suspension (NDA 21-132).

We acknowledge receipt of your submissions dated January 26, March 2, March 4, March 12, April 19, May 13, June 7, June 16, June 18, and June 22, 2004.

These supplemental new drug applications provide for the use of Zyvox™ Tablets, Zyvox™ IV Injection and Zyvox™ Oral Suspension for the treatment of:

1. Community Acquired Pneumonia caused by *S. pneumoniae* (including multi-drug resistant strains, [MDRSP])
2. Nosocomial Pneumonia caused by *S. pneumoniae* (including multi-drug resistant strains, [MDRSP]).

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.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted on June 22, 2004.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-130/S-006, NDA 21-131/S-007, and NDA 21-132/S-006." Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated June 22, 2004. The commitment is listed below.

1. The antibiotics included in the current FDA definition of multi-drug resistant *Streptococcus pneumoniae* (MDRSP) are primarily used in the treatment of patients with community-acquired pneumonia and are not representative of the antibiotics commonly used to treat patients with hospital-acquired pneumonia (HAP). In order to provide antimicrobial susceptibility data that is more relevant to the treatment of patients with HAP due to MDRSP, the sponsor is requested to perform additional susceptibility testing of the clinical MDRSP isolates from patients with HAP. A list of suitable antibiotics will be provided by the Agency at a later date.

Final report submission: by June, 2005

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled “**Postmarketing Study Protocol**”, “**Postmarketing Study Final Report**”, or “**Postmarketing Study Correspondence**.”

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).

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If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and

Enclosure: Patient package insert

**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

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