



NDA 21-130/S-005
NDA 21-131/S-006
NDA 21-132/S-005

Pharmacia & Upjohn
c/o Pfizer, Inc.
Attention: Roberta Krieger
Associate Director
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Ms. Krieger:

Please refer to your supplemental new drug applications dated September 26, 2003, received September 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for

NDA 21-130/S-005, Zyvox™ Tablets, (linezolid)

NDA 21-131/S-006, Zyvox™ IV Injection, (linezolid)

NDA 21-132/S-005, Zyvox™ for Oral Suspension (linezolid)

We also acknowledge your submissions dated November 14, 2003.

These “Changes Being Effected” supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled “ Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use” (68FR 6062, February 6, 2003)

We completed our review of these applications and they are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted September 26, 2003. 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, this submission should be designated "FPL for approved supplements NDA 21-130/S-005, NDA 21-131/S-006, and NDA 21-132/S-005." Approval of this submission by FDA is not required before the labeling is used.

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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 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 Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Janice Soreth
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