



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-130/S-008 and S-009
NDA 21-131/S-009 and S-010
NDA 21-132/S-008 and S-009

Pfizer Inc.
Attention: James Symons, Ph.D.
Global Regulatory Leader
2800 Plymouth Road
Ann Arbor, MI 48105

Dear Dr. Symons:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act as follows:

Name	NDA/Supplement	Dated	Received on
Zyvox [®] (linezolid) tablets	NDA 21-130/S-008	September 14, 2004	September 15, 2004
Zyvox [®] (linezolid) injection	NDA 21-131/S-009	September 14, 2004	September 15, 2004
Zyvox [®] (linezolid) for oral suspension	NDA 21-132/S-008	September 14, 2004	September 15, 2004
Zyvox [®] (linezolid) tablets	NDA 21-130/S-009	December 16, 2004	December 17, 2004
Zyvox [®] (linezolid) injection	NDA 21-131/S-010	December 16, 2004	December 17, 2004
Zyvox [®] (linezolid) for oral suspension	NDA 21-132/S-009	December 16, 2004	December 17, 2004

We acknowledge receipt of your submissions dated October 15, 2004 and April 22, 2005, for NDA 21-130/S-008, NDA 21-131/S-009, NDA 21-132/S-008, amending the supplements submitted September 14, 2004.

“Changes Being Effected” supplemental new drug applications NDA 21-130/S-008, NDA 21-131/S-009, NDA 21-132/S-008, submitted September 14, 2004, provide for revisions to the **PRECAUTIONS** and **Postmarketing experience** sections of the package insert to update the existing language regarding reports of optic neuropathy.

Prior approval supplemental new drug applications NDA 21-130/S-009, NDA 21-131/S-010, NDA 21-132/S-009, submitted December 16, 2004, provide for revisions to the package insert to update information regarding pharmacokinetics of linezolid in the cerebrospinal fluid in pediatric patients, and to update information on the clinical efficacy of linezolid in pediatric patients with infections due to vancomycin-resistant enterococci.

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.

The final printed labeling (FPL) must be identical to the enclosed text for the package insert.

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

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on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements** NDA 21-130/S-008 and S-009, NDA 21-131/S-009, and S-010, and NDA 21-132/S-008 and S-009." 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.

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) 827-0391.

Sincerely,

{See appended electronic signature page}

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

Enclosure: 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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