PHARMACIA

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IMPORTANT DRUG WARNING

((DATE))

Dear Health Care Professional:

This letter is to advise you of important, new, safety information that has been added to the prescribing information for ZYVOX™ (linezolid injection, tablets and for oral suspension), a synthetic antibacterial agent of the oxazolidinone class. ZYVOX is indicated for the treatment of adult patients with the following infections caused by susceptible strains of designated microorganisms: vancomycin–resistant *Enterococcus faecium*, including cases with concurrent bacteremia; nosocomial pneumonia; complicated and uncomplicated skin and skin structure infections; and community-acquired pneumonia, including cases with concurrent bacteremia.

Pharmacia and the U. S. Food and Drug Administration (FDA) have received reports from the spontaneous reporting system of myelosuppression in patients receiving ZYVOX.

To communicate this important safety information, the following has been added to the WARNINGS section of the labeling:

> **Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving linezolid. In cases where the outcome is known, when linezolid was discontinued, the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks, those with pre-existing myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or those with a chronic infection who have received previous or concomitant antibiotic therapy. Discontinuation of therapy with linezolid should be considered in patients who develop or have worsening myelosuppression.**

Changes consistent with the added warning have been made to the ADVERSE REACTIONS section and are as follows:

> **Postmarketing Experience**
> Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported during postmarketing use of ZYVOX (see **WARNINGS**). These events have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ZYVOX, or a combination of these factors. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made and a causal relationship cannot be precisely established.

Our primary concern is the safety and well-being of patients who receive ZYVOX. If you become aware of any case(s) of the events described above, in patients treated with ZYVOX, please report the event promptly. You may contact Pharmacia at 1-800-253-8600 extension 38244, or the FDA MedWatch program, by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, or by mail to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20857, or by the Internet at https://www.accessdata.fda.gov/scripts/medwatch/.

Sincerely,

((signature))

Janet Peterson, PhD
Global Director, Infectious Diseases–GMA

Enclosure: Full prescribing information for ZYVOX™ (linezolid injection, tablets, and for oral suspension).