DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-130/S-003
NDA 21-131/S-003
NDA 21-132/S-003

Pharmacia & Upjohn Company
Attention: Robert S. Gremban
Regulatory Affairs Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. Gremban:

Please refer to your supplemental new drug applications dated June 21, 2002, received June 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyvox™ (linezolid tablets) Tablets, 400 and 600 mg (NDA 21-130/S-003); Zyvox™ (linezolid injection) I.V. Injection, 200 mg/100 mL, 400 mg/200 mL, and 600 mg/300 mL bags (NDA 21-131/S-003); and Zyvox™ (linezolid for oral suspension) for Oral Suspension, 100 mg/5 mL (NDA 21-132/S-003).

We acknowledge receipt of your submissions dated July 17, August 7, August 16, October 2, October 23, November 6, November 11, November 15, November 18, November 26, December 6, and December 18, 2002.

These supplemental new drug applications provide for the use of Zyvox™ (linezolid) Tablets, I.V. Injection, and for Oral Suspension for the treatment of pediatric patients with nosocomial pneumonia, community-acquired pneumonia, complicated and uncomplicated skin and skin structure infections, and vancomycin-resistant *Enterococcus faecium* infections.

We completed our review of these applications, as amended. These applications 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 (text for the package insert) submitted December 18, 2002.

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 ten 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-003, NDA 21-131/S-003, and NDA 21-132/S-003." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
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 Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{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

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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