



NDA 21130/S-022  
NDA 21131/S-020  
NDA 21132/S-021

**SUPPLEMENT APPROVAL**

Pfizer Global Pharmaceuticals  
Attention: Nadia D. Kirzecky, Ph.D.  
Associate Director, Worldwide Regulatory Strategy  
235 East 42nd Street  
New York, NY 10017

Dear Dr. Kirzecky:

Please refer to your Supplemental New Drug Application (sNDA) dated June 28, 2010, received June 28, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement Number	Name of Drug Products:
21-130	022	Zyvox <sup>®</sup> (linezolid) tablets
21-131	020	Zyvox <sup>®</sup> (linezolid) IV Injection
21-132	021	Zyvox <sup>®</sup> (linezolid) for oral Suspension

We acknowledge receipt of your submission dated June 28, 2010.

These “Prior Approval” supplemental new drug applications provide for the changes proposed in our supplement request letter dated May 14, 2010 to update the product label to include the following language:

**CLINICAL PHARMACOLOGY**

**Pharmacodynamics**

In a randomized, positive- and placebo-controlled crossover thorough QT study, 40 healthy subjects were administered a single ZYVOX 600 mg dose via a 1 hour IV infusion, a single ZYVOX 1200 mg dose via a 1 hour IV infusion, placebo, and a single oral dose of positive control. At both the 600 mg and 1200 mg ZYVOX doses, no significant effect on QTc interval was detected at peak plasma concentration or at any other time.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text which is identical to the content of labeling submitted on June 28, 2010.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling submitted on June 28, 2010 and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
5600 Fishers Lane  
Rockville, MD 20857

## **REPORTING REQUIREMENTS**

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) 796-0734.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, M.D., MPH  
Deputy Director for Safety  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21132	SUPPL-21	PHARMACIA AND UPJOHN CO	ZYVOX
NDA-21131	SUPPL-20	PHARMACIA AND UPJOHN CO	ZYVOX
NDA-21130	SUPPL-22	PHARMACIA AND UPJOHN CO	ZYVOX

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

---

SUMATHI NAMBIAR  
07/16/2010