



NDA 21-130/S-034  
NDA 21-131/S-028  
NDA 21-132/S-033

## SUPPLEMENT APPROVALS

Pharmacia & Upjohn Company  
a subsidiary of Pfizer, Inc.  
Attention: Nadia D. Kirzecky  
Director, Pfizer Essential Health Global Regulatory Affairs Brands  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Dear Ms. Kirzecky:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 9, 2015, received April 9, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 21-130/S-034: Zyvox (linezolid) Tablets, 400 mg and 600 mg
- NDA 21-131/S-028: Zyvox (linezolid) Injection, 2 mg/mL
- NDA 21-132/S-033: Zyvox (linezolid) Suspension, 100 mg/5mL

We also acknowledge receipt of your amendments dated October 7, 2016, which constituted a complete response to our June 6, 2016, action letter.

These supplemental applications, submitted as “Changes Being Effected in 30 days” supplements, propose the introduction of an additional peel-off bar code label for Zyvox Injection, which can be transferred from the overwrap to the inner bag by an appropriate health care professional or other hospital personnel at the time of use.

Additionally, these supplements provide for revisions addressing the peel-off bar code label to the **HIGHLIGHTS, DOSAGE AND ADMINISTRATION, Intravenous administration**, subsection (2.2) and **HOW SUPPLIED/STORAGE AND HANDLING, Injection**, subsections (16.1 and 16.4), and revisions addressing the removal of the 200 mL presentation in the **DOSAGE FORMS AND STRENGTHS (3.0)** and **DESCRIPTION (11.0)** sections of the Zyvox prescribing information, along with minor editorial revisions.

## **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 that include labeling changes for these NDAs, including 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 these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## **PEEL-OFF IMMEDIATE CONTAINER LABELS**

Submit final peel-off printed immediate container labels that are identical to the enclosed peel-off immediate container labels submitted on February 7, 2017, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)*.

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate these submissions as “**Final Printed Peel-Off Container Labels for approved NDA 21-130/S-034, NDA 21-131/S-028 and NDA 21-132/S-033.**” Approval of these submissions by FDA is not required before the labeling is used.

### **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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

Joseph Toerner, MD, MPH  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURES:      Content of Labeling  
                         Peel-Off Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOSEPH G TOERNER  
07/13/2017