NDA 21-130/S-039 & S-040
NDA 21-131/S-034 & S-035
NDA 21-132/S-038 & S-039

SUPPLEMENT APPROVALS

Pharmacia & Upjohn Company
a subsidiary of Pfizer, Inc.
Attention: Anna Maria Gambino, MBA
Director, Global Regulatory Affairs, Hospital Business Unit
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Gambino:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 17, 2019 (PLLR), and December 10, 2019 (removal of barcode). We also refer to your amendments for these supplements, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 21-130/S-039 & S-040: Zyvox (linezolid) Tablets, 600 mg
- NDA 21-131/S-034 & S-035: Zyvox (linezolid) Injection, 2 mg/mL
- NDA 21-132/S-038 & S-039: Zyvox (linezolid) for Oral Suspension, 100 mg/5 mL

These Prior Approval supplemental new drug applications provide for revisions to the prescribing information (PI) in order to comply with the Pregnancy and Lactation Labeling Rule (PLLR) and to address removal of the peel-off barcode label and to align with USP Chapter 7 to express concentrations in quantity per milliliter (quantity/mL).

More specifically, revisions have been made to the **HIGHLIGHTS OF PRESCRIBING INFORMATION, FULL PRESCRIBING INFORMATION: CONTENTS, INDICATIONS AND USAGE (1)** sections, **DOSAGE AND ADMINISTRATION (2)** section**, Intravenous Administration (2.2)** subsection, **DOSAGE FORMS AND STRENGTHS (3)** section, **WARNINGS AND PRECAUTIONS (5)** section, **Risks in Patients with Phenylketonuria (5.10)** subsection, **USE IN SPECIFIC POPULATIONS (8)** section, **Pregnancy (8.1), Lactation (8.2),** and **Females and Males of Reproductive Potential (8.3)** subsections, **DESCRIPTION (11)** section**, NONCLINCIAL TOXICOLOGY (13)** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection, **HOW SUPPLIED/STORAGE AND HANDLING (16)** section, and **PATIENT COUNSELING INFORMATION (17)** section. In addition, minor editorial revisions have been made throughout the prescribing information.

CARTON AND CONTAINER

We also note that the statement "**DISCARD UNUSED PORTION**" will be added to the carton and container labeling for Zyvox (linezolid) Injection in the next annual report.

APPROVAL & LABELING

We have 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 enclosed agreed-upon labeling, with the minor editorial revisions listed below and reflected in the enclosed labeling:

- In the **PATIENT COUNSELING INFORMATION (17)** section**, Diarrhea** subsection, the term "antibiotic(s)" was replaced to read "antibacterial drug(s)".

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the prescribing information) 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE: Perscribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
08/05/2020 10:46:38 AM