NDA 21-130/S-041
NDA 21-131/S-037
NDA 21-132/S-040

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 (sNDA) dated October 16, 2020, received October 16, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 21-130/S-041: Zyvox (linezolid) Tablets, 600 mg
- NDA 21-131/S-037: Zyvox (linezolid) Injection, 2 mg/mL
- NDA 21-132/S-040: Zyvox (linezolid) for Oral Suspension, 100 mg/5 mL

These "Changes Being Effected" supplemental new drug applications provide for the addition of the term "hypersensitivity vasculitis" to the **ADVERSE REACTIONS (6)** section, **Postmarketing experience (6.2)** subsection of the prescribing information.

APPROVAL & LABELING

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

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]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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. If the content of labeling in SPL format initially submitted with these CBE-0 labeling supplements is identical to the attached approved labeling, an additional submission of content of the labeling in SPL format is not required.

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).

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: Prescribing Informtion

[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.

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
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