NDA 21-130/S-042
NDA 21-131/S-038
NDA 21-132/S-041

SUPPLEMENT APPROVALS

Pfizer, Inc.
Attention: Alka Abrol, RAC
Manager, Global Regulatory Affairs
Hospital Business Unit, Pfizer Biopharmaceutical Group
235 East 42nd Street
New York, NY 10017

Dear Ms. Abrol:

Please refer to your supplemental new drug applications (sNDAs) dated April 13, 2021, received April 13, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 21-130/S-042 Zyvox (linezolid) Tablets, 600 mg
- NDA 21-131/S-038 Zyvox (linezolid) Injection, 2 mg/mL
- NDA 21-132/S-041 Zyvox (linezolid) Oral Suspension, 100 mg/5 mL

These "Changes Being Effected" sNDAs provide for updates to the **WARNINGS AND PRECAUTIONS (5), Serotonin Syndrome (5.3)** subsection, **ADVERSE REACTIONS (6)**, **Postmarketing Experience (6.2)** subsection and **PATIENT COUNSELING INFORMATION (17)** sections of the prescribing information pertaining to revisions as they relate to serotonin syndrome and opioids. In addition, minor editorial revisions were made throughout the PI.

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 and with minor editorial revisions to **HIGHLIGHTS of PRESCRIBING INFORMATION** and **Subsection 6.2** (underlined) below:

- The term "Optic Neuropathy" was updated to Title case in **HIGHLIGHTS of PRESCRIBING INFORMATION**

- **Section 6.2:** "Serotonin syndrome has been reported in patients receiving concomitant serotonergic agents, including antidepressants such as selective serotonin reuptake inhibitors (SSRIs) and opioids, and ZYVOX *[see Warnings and Precautions (5.3)]*."

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).

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 Information

[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.

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
09/01/2021 01:23:22 PM