NDA 50-138/S-242
NDA 50-141/S-238

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Mikhail Abarshalin
Senior Manager, Pfizer Global Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Abarshalin,

Please refer to your supplemental new drug applications (sNDAs) dated September 17, 2019, received September 17, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for for Bicillin C-R (penicillin G benzathine and penicillin G procaine) Injectable Suspension (NDA 50-138) and Bicillin L-A (penicillin G benzathine) Injectable Suspension (NDA 50-141).

These "Changes Being Effected" supplemental new drug applications provide for inclusion of the information regarding Severe Cutaneous Adverse Reactions (SCAR) in the **WARNINGS** section of the prescribing information (PIs).

APPROVAL & LABELING

We have completed our review of these applications. 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] 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

[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.

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 approved NDAs (21 CFR 314.80 and 314.81).

If you have any questions, call Eva Zuffova, PhD, Regulatory Project Manager, at (301) 796-0697.

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

ENCLOSURES:

- Content of Labeling
    - Prescribing Informations

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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