DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-551/S-043

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Shai Srulovich, PharmD, RPh
Senior Manager, Worldwide Safety and Regulatory
235 East 42nd Street
New York, NY 10017-7555

Dear Mr. Srulovich:

Please refer to your Supplemental New Drug Application (sNDA) dated October 28, 2013, received October 28, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cefobid (sterile cefoperazone) Injection.

We also acknowledge receipt of your amendments dated September 10, 2014, and March 6, 2015.

The September 10, 2014, submission constituted a complete response to our April 11, 2014, action letter.

This "Changes Being Effected" supplemental new drug application provides for updates to the **WARNINGS** and **ADVERSE REACTIONS** sections of the package insert. In addition, the package insert has been revised as follows:

- Revisions to meet the requirements for the Labeling for Systemic Antibacterial Drugs (21 CFR 201.24).

- The **CLINICAL PHARMACOLOGY, Microbiology** subsection has been revised to update the susceptibility test interpretive criteria and quality control parameters.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and in the enclosed labeling.

The following text (as annotated in the attached label) should be added as a note to Table 2, immediately before footnotes a and b:

- Methicillin-susceptible *Staphylococcus* spp., as determined by susceptibility to oxacillin can be considered susceptible to cefoperazone.

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, except with the revisions annotated in 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/U CM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, 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 with the revisions indicated above approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
03/18/2015