DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 050138/S-238
NDA 050141/S-235

SUPPLEMENT APPROVAL

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

Dear Mr. Abarshalin:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received October 31, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bicillin C-R (penicillin G benzathine and penicillin G procaine) Injectable Suspension (NDA 050138) and Bicillin L-A (penicillin G benzathine) Injectable Suspension (NDA 050141).

These Prior Approval supplemental new drug applications revise the container label and carton labeling as requested in our October 6, 2017, letter.

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on October 31, 2017, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 050138/S-238, NDA 050141/S-235**." Approval of these submissions by FDA is not required before the labeling is used.

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Carton, Container Labeling

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

/s/

JOSEPH G TOERNER
12/07/2017