NDA 018484/S-028

SUPPLEMENT APPROVAL

Pfizer Inc
Attention: Karen Baker, MS
Director, Pfizer Essential Health Global Regulatory Affairs R&D
235 East 42nd Street
New York, NY 10017-7555

Dear Ms. Baker:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 18, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prostin VR Pediatric (alprostadil injection, USP).

This Prior Approval supplemental new drug application provides for container and carton labels for Prostin VR Pediatric (alprostadil injection, USP) Sterile Solution, revised per the global initiative

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels, 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 018484/S-028.**" Approval of this submission 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 Abolade (Bola) Adeolu, Regulatory Business Process Manager, at (301) 796 - 4264.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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