NDA 204485/S-026

**SUPPLEMENT APPROVAL**

Par Sterile Products, LLC
Attention: Brandy Van Camp
Manager, Regulatory Affairs
Six Ram Ridge Road
Chestnut Ridge, NY 10977

Dear Ms. Van Camp:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 23, 2022, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasostrict (vasopressin injection, USP).

This "Changes Being Effected" supplemental new drug application provides for labeling revision per the Agency's request dated April 29, 2022 to include the quantitative information of inactive ingredients in the carton and container labels as stated in Prescribing Information, section 11 Description.

## 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.

## CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 204485/S-026.**" 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 Elizabeth Markovich, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

*{See appended electronic signature page}*

*For:*
Gurpreet Gill-Sangha, PhD
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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