



NDA 204485/S-025

SUPPLEMENT APPROVAL

Par Sterile Products, LLC
Attention: Carla English
Director, Regulatory Affairs
Six Ram Ridge Road
Chestnut Ridge, NY 10977

Dear Carla English:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 21, 2022, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasopressin (vasopressin injection, USP), 20 units/100 mL, 40 units/100 mL, and 60 units/100 mL.

This “Changes Being Effected” supplemental new drug application provides for the addition of “In 5 % Dextrose” to the carton and container labeling for Vasopressin 20 units/100 mL, 40 units/100 mL and 60 units/100 mL single dose presentations.

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-025.**” 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, MPH, Regulatory Business Process Manager, at (301) 796 - 5071.

Sincerely,

{See appended electronic signature page}

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:

Carton and Container Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 9/14/2022 07:45:48PM
GUID: 5135f2ad000117842392c50c36c7f28a