DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204485/S-002

SUPPLEMENT APPROVAL

PAR Sterile Products, LLC
Attention: Gerald Vasquez, Sr. Manager Regulatory Affairs
One Upper Pond Road
Building D, 3rd floor
Parsippany, NJ 07054

Dear Mr. Vasquez:

Please refer to your Supplemental New Drug Application (sNDA) dated February 12, 2015, received February 12, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasostrict (vasopressin) Injection.

We acknowledge receipt of your amendments dated March 13, 2015, April 17, 2015 and May 5, 2015.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for 12 months room temperature storage following storage at refrigerated conditions for up to 24 months.

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. We remind you of your following commitments:

1) To update your content of labeling and carton label per our Information Request dated May 5, 2015.
2) To continue in-use stability studies to confirm product quality after 12 months room temperature storage following storage at refrigerated conditions.

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 revised per your May 5, 2015 commitment, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, 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/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes 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 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are revised per your May 5, 2015 commitment, 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 (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 204485/S-002**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 Olga Simakova, Regulatory Project Manager, at (240) 402-3814.

Sincerely,

Wendy I. Wilson -S

Digitally signed by Wendy I. Wilson -S
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Date: 2015.05.07 10:24:04 -04'00'

Wendy Wilson-Lee, PhD
Branch Chief, Branch I (Acting)
Division of New Drug Products I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton Labeling