NDA 204485/S-017

SUPPLEMENT APPROVAL

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

Dear Ms. English:

Please refer to your Supplemental New Drug Application (sNDA) dated October 9, 2020, received October 9, 2020, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasostrict (vasopressin injection, USP).

We also refer to our approval letter dated March 15, 2021, which contained the following error: Supplement approved as a PAS instead of CBE.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain March 15, 2021, the date of the original approval letter.

This Changes Being Effected supplemental new drug application provides for: Updated labeling description section for identity of sodium hydroxide and hydrochloric acid as pH adjusters, and update quantities of inactive ingredients as per the Agency's Supplement request letter dated September 9, 2020.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed- upon labeling.

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 identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 notations, including supplement number(s) and annual reportable date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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}

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:
Prescribing Information

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
Date: 3/22/2021 01:56:57PM
GUID: 5135f2ad000117842392c50c36c7f28a