

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

204485Orig1s000

Trade Name: Vasostrict

Generic Name: vasopressin injection, USP

Sponsor: Par Sterile Products, LLC

Approval Date: April 17, 2014

Indications: Vasostrict (vasopressin injection, USP) is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

CENTER FOR DRUG EVALUATION AND RESEARCH

204485Orig1s000

CONTENTS

Reviews / Information Included in this NDA Review.

| | |
|---|----------|
| Approval Letter | X |
| Other Action Letters | X |
| Labeling | X |
| REMS | |
| Summary Review | X |
| Officer/Employee List | X |
| Office Director Memo | |
| Cross Discipline Team Leader Review | |
| Medical Review(s) | X |
| Chemistry Review(s) | X |
| Environmental Assessment | |
| Pharmacology Review(s) | X |
| Statistical Review(s) | X |
| Microbiology / Virology Review(s) | X |
| Clinical Pharmacology/Biopharmaceutics Review(s) | X |
| Other Reviews | X |
| Risk Assessment and Risk Mitigation Review(s) | |
| Proprietary Name Review(s) | X |
| Administrative/Correspondence Document(s) | X |

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204485Orig1s000

APPROVAL LETTER



NDA 204485

NDA APPROVAL

Par Sterile Products, LLC
Attention: Mr. Gerald Vasquez
Morris Corporate Center 2
One Upper Pond Road
Building D, 3rd Floor
Parsippany, NJ 07054

Dear Mr. Vasquez:

Please refer to your New Drug Application (NDA) dated September 25, 2012, received September 26, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vasopressin (vasopressin injection, USP), 20 units per mL.

We acknowledge receipt of your amendments dated October 18, November 18, December 17 and 23, 2013, and February 25, March 4, 6, 18, and 28 (two), April 7 and 14, 2014.

The October 18, 2013 submission constituted a complete response to our July 19, 2013 action letter.

This new drug application provides for the use of Vasopressin (vasopressin injection, USP) to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines.

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

A 12-month expiration dating period is granted for Vasopressin (vasopressin injection, USP), 20 units per mL, stored in the proposed container/closure system at the recommended storage condition, between 15°C and 25°C (59°F and 77°F).

We acknowledge your Safety Update submitted on October 18, 2013 and we agree that there are no novel safety concerns based on your submission.

We note that your April 14, 2014 submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels submitted on April 7, 2014 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.**” Approval of this submission by FDA is not required before the labeling is used.

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

ADVISORY COMMITTEE

Your application for vasopressin was not referred to an FDA advisory committee because outside expertise was not necessary; there were no controversial issues that would benefit from advisory committee discussion.

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.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. In the sole published prospective study of vasopressin in pediatric patients with vasodilatory shock (Choong et. al.), a total of 512 patients were screened over 4 years, in order to enroll only 69 patients. Attempts to obtain further data related to this published study were unsuccessful.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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, please contact:

Quynh Nguyen, Pharm.D., RAC
Regulatory Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

NORMAN L STOCKBRIDGE
04/17/2014