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July 21, 2017

Sharon Hertz, M.D.
Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthetics, Analgesia and Addiction Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 203826 - PHENYLEPHRINE HYDROCHLORIDE INJECTION, USP 10 mg/mL, 1 mL Vial

- **RESPONSE TO PREA NON-COMPLIANCE LETTER**
- **DEFERRAL EXTENSION REQUESTED**

Dear Dr. Hertz:

Reference is made to West-Ward Pharmaceuticals Corp.'s New Drug Application (NDA) for Phenylephrine HCl Injection, USP, 10 mg/mL, packaged as 1 mL (b) (4) single dose vials, approved under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act.

Additional reference is made to the postmarketing requirement (PMR 1991-1) of the Pediatric Research Equity Act (PREA) for this application which required submission of the pediatric assessment by May 23, 2017. Further reference is made to the Agency's letter dated June 8, 2017.

Reference is also made to the Clinical Pediatric Study Protocol 1420-RDP-009 Amendment 2 (Version 3.0), submitted on February 25, 2016 to IND 109977.
During the course of this study three study sites have closed due to lack of enrollment. At present seven sites are currently recruiting study subjects throughout the United States. To date a total of 29 study subjects have been dosed.

Regulatory Affairs
West-Ward Pharmaceuticals Corp.
2 Esterbrook Lane, Cherry Hill, NJ 08003
Tel: 856.489.2247 | Fax: 856.424.1461
www.west-ward.com

The protocol states:

- "A sufficient number of subjects will be enrolled in this study in order to assure that 100 subjects will experience a decrease in BP that requires treatment and will receive PHI (50 subjects via infusion and 50 subjects as a bolus.)"

Due to the lack of enrollment, it was not possible to enroll the number of study subjects required to comply with the goal dates of completion of the study by December 20, 2016 with the final report submission by May 23, 2017.

Enclosed in Module 1.9.2 is a summary of current enrollment along with the anticipated future enrollment rate. Given the inherent challenges to enrollment in this pediatric study and based on the enrollment rate to date, and in accordance with 21 CFR 315.55(b), we wish to request deferral extensions of the trial completion date to June 30, 2022 and to the final report submission date to December 30, 2022. See Module 1.9.2 Request for Deferral Extension of Pediatric Studies.

We look forward to your response regarding these proposals. Please contact me or Frances Cacchio, (phone) 856-489-5607, (email) fcacchio@west-ward.com if you require any additional information.

Sincerely,

J. Barton Kalis

J. Barton Kalis
Senior Director, Regulatory Affairs
West-Ward Pharmaceuticals Corp.
Phone: 856-489-2247
Email: jkalis@west-ward.com

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