DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 204300/S-005

SUPPLEMENT APPROVAL

Éclat Pharmaceuticals
c/o The Weinberg Group Inc.
1129 Twentieth Street, NW, Suite 600
Washington, DC 20036

Attention: Marla E. Scarola, MS
Senior Consultant

Dear Ms. Scarola:

Please refer to your Supplemental New Drug Application (sNDA) dated April 23, 2015, received April 23, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vazculep (Phenylephrine Hydrochloride Injection, USP, 1%) 10 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the carton and container labels:

50 mg/5 mL carton and container:

- Color of box containing strength has been changed (b) (4) to gold
- Color of text listing strength has been changed (b) (4) to black
- Pharmacy bulk package statement has been highlighted in yellow

100 mg/10 mL carton and container:

- Pharmacy bulk package statement has been highlighted in yellow

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your April 23, 2015, submission containing final printed carton and container labels.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory

comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. 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, contact Kimberly Compton, RPh, Senior Regulatory Project Manager at 301-796-1191.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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

/s/

SHARON H HERTZ
05/28/2015