NDA 204300/S-011

SUPPLEMENT APPROVAL

Avadel Legacy Pharmaceuticals
c/o The Weinberg Group
1129 Twentieth Street NW
Suite 600
Washington, DC 20036

Attention: Marla E. Scarola, MS
Vice President, Regulatory Program Management

Dear Ms. Scarola:

Please refer to your supplemental new drug application (sNDA) dated and received September 20, 2019, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VAZCULEP (phenylephrine hydrochloride, USP) injection. We also refer to your amendments dated October 29, 2019 and January 29, 2020.

This Prior Approval supplemental new drug application provides for the following revisions to single-dose container label, carton labeling and pharmacy bulk package container labels:

- Added the statement: "*The Pharmacy Bulk Vial is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area)*" to the side panel of the container label and carton labeling of the, 50 mg/5 mL Pharmacy Bulk Package and 100 mg/10 mL Pharmacy Bulk Package. This revision was also made on the 100 mg/10 mL Pharmacy Bulk Package container label and carton labeling for Avadel's new private label distributor- BluePoint.

- Added the statement: "*Dispensing from a pharmacy bulk vial should be completed within 4 hours after the vial is penetrated*" to the 50 mg/5 mL Pharmacy Bulk Package and 100 mg/10 mL Pharmacy Bulk Package container labels. This revision was also made on the BluePoint 100 mg/10 mL Pharmacy Bulk Package container label.

- Revised the beyond use date statement on container labels for the 50 mg/5 mL Pharmacy Bulk Package and 100 mg/10 mL Pharmacy Bulk Package from (b) (4) to the following: "*Discard after __/__/__ Time _____ (AM/PM)".* This revision was also made to the container label for the 100 mg/10 mL Pharmacy Bulk Package distributed by Avadel's private label distributor, BluePoint.

- Revised the statement "*Single-Dose Vial*" to read: "*Single-Dose Vial – Discard Unused Portion*" on the carton labeling for the 10 mg/mL single-dose presentation.

- Included product identifiers to the carton labeling for the 10 mg/mL single-dose presentation and to the 100 mg/10 mL Pharmacy Bulk Package. This revision was also made on the BluePoint 100 mg/10 mL Pharmacy Bulk Package carton labeling.

APPROVAL & LABELING

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.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling and carton and container labeling submitted on September 20, 2019, October 29, 2019 and January 29, 2020 as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 204300/S-011**." Approval of this submission by FDA is not required before the labeling is used.

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 Prescribing Information to:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and*

Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.[1]

You must submit final promotional materials and Prescribing Information, 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 FDA.gov.[2] Information and Instructions for completing the form can be found at FDA.gov.[3] For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.[4]

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 Taiye Adedeji, PharmD, Regulatory Project Manager, at (240) 402-8561.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca,
Acting Division Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[1] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[2] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf
[4] http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RIGOBERTO A ROCA
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