NDA 204630/S-010

SUPPLEMENT APPROVAL

Provepharm SAS
c/o Clinipace Inc.
Attention: Clara Li
VP Regulatory & Strategic Development
1434 Spruce Street, Suite 100
Boulder, CO 80302

Dear Ms. Li:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 23, 2020, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PROVAYBLUE® (methylene blue) injection USP.

This "Changes Being Effected" supplemental new drug application provides for changes to the format of the barcode on the 10 mL ampule label from the Code 128 format to the GS1 DataBar Limited format that was on the previously approved version of the ampule label.

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.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 204630/S-010.**" Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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