NDA 216264/S-001

**SUPPLEMENT APPROVAL**

Provepharm SAS
c/o Provepharm Inc
Attention: Marc Tokars
100 Springhouse Drive, Suite 105
Collegeville, PA 19426

Dear Mr. Tokars:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 17, 2022, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bludigo (indigotindisulfonate sodium injection).

This "Changes Being Effected" supplemental new drug application provides for labeling changes that includes updates and modification to the design of the product carton and 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 216264/S-001.**" 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 (21 CFR 314.80 and 314.81).

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

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:

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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