NDA 207987/S-002

APPROVAL LETTER

Bpi Labs LLC
Attention: Sreekanth Cheripalli
Sr. Manager, Regulatory Affairs
12393 Belcher Rd S.
Suite 450
Largo, FL 33777-1641

Dear Sreekanth Cheripalli:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 27, 2024, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ablysinol (dehydrated alcohol) injection.

We acknowledge receipt of your amendment dated November 8, 2024, which constituted a complete response to our July 11, 2024, action letter.

This Prior Approval supplemental new drug application provides for: the following changes.

- Addition of a new 5 mL Vial presentation of ABLYSINOL (dehydrated alcohol) Injection packaged in an alternate container closure system consisting of 5 mL Type (b) (4) Glass Vials and (b) (4) rubber stoppers.
- Addition of BPI Labs, LLC (b) (4) located in Largo, Florida [FEI Number 3015156709] as an alternate drug product manufacturing, release testing, stability testing, stability sample storage, and distribution site.
- Addition of an alternate drug product manufacturing technique at (b) (4) (b) (4) involving (b) (4) (b) (4)
- Addition of BPI Labs, LLC (b) (4) located in Largo, Florida [FEI Number 3015156709] as an alternate drug product packaging, labeling (b) (4) site.
- Tightening of the acceptance criterion for the Endotoxin test parameter in the drug substance specification from < (b) (4) EU/mg to < (b) (4) EU/mg and addition of both TAMC and TYMC test parameters to the drug substance specification with reference to an update to DMF (b) (4).
- Addition of (b) (4) (b) (4) as an alternate analytical facility for (b) (4) (b) (4)
- Addition of (b) (4) (b) (4) as an analytical facility for (b) (4) (b) (4)

APPROVAL & LABELING

We have completed our review of this supplemental 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 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 207987/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

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 Grafton Adams, Senior Regulatory Business Process Manager, at (240) 402 - 7765.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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