



NDA 005939/S-017

SUPPLEMENT APPROVAL

Provepharm SAS
c/o Provepharm Inc.
Attention: Rahul Poria
Director, Regulatory Affairs
100 Springhouse Drive
Suite 105
Collegeville, PA 19426

Dear Rahul Poria:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 19, 2025, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BAL in Oil Ampules (Dimercaprol Injection, USP).

This “Changes Being Effected” supplemental new drug application provides for revisions to the drug product Carton and Container labels to reflect change in application ownership, and additional layouts of the labels.

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 005939/S-017.**” Approval of this submission by FDA is not required before the labeling is used.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(I)(1)(i)] (if applicable), in MS Word format, that includes the changes approved in this supplemental application, as

well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Oluwafunmike (Funke) Ajomale, Regulatory Business Process Manager, at oluwafunmike.ajomale@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
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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