NDA 205098/S-051

APPROVAL LETTER

Provensis Limited
Attention: Melissa Young
Director, Regulatory Affairs
1 Scimed Place
Maple Grove, MN 55311
melissa.young@bsci.com

Dear Melissa Young:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 21, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VARITHENA (polidocanol injectable foam).

This Prior Approval supplemental new drug application provides for:

- to remove references to [redacted] (b) (4) and update the labeling to reflect the change.
- to align references to alcohol content in labeling to align with USP General Notices and Requirements 2.20 Official Articles and 21 CFR 201.10(d)(2) requirements.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

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(l)(1)(i)] 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).

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 ensure all labeling includes expiration dates, lot numbers and product identifiers, including the format. 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 205098/S-051.**" 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, contact Rajani Ranga, Regulatory Business Process Manager, at Rajani.Ranga@fda.hhs.gov or 2404025041.

Sincerely,

{See appended electronic signature page}

Julia Pinto, Ph.D.
Supervisor, Division of Product Quality Assessment VIII
Office of Product Quality Assessment II
Office of Pharmaceutical Quality

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Julia Pinto

Digitally signed by Julia Pinto
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