NDA 208854/S-007

SUPPLEMENT APPROVAL

BioDelivery Sciences Internation, Inc.
Attention: Josephine Voisinet
Senior Manager, Regulatory Affairs
100 Technology Center Drive
Suite 300
Stoughton, MA 02072

Dear Josephine Voisinet:

Please refer to your supplemental new drug application (sNDA) dated and received, July 3, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Symproic (naldemedine) tablets.

This "Changes Being Effected" sNDA provides updates to the Warnings and Precautions, subsection 5.1 Gastrointestinal Perforation of the Prescribing Information (PI) to describe postmarketing cases of gastrointestinal (GI) perforation, including fatal cases, when Symproic was used in patients at risk of GI perforation and addition of subsection 6.2 Postmarketing Experience to the Adverse Reactions section to include GI perforation.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling:

- Added a horizontal line on the first page of the PI below the Table of Contents.
- Italicized the cross-reference to Warnings and Precautions (5.1) in subsection 6.2 of the PI.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and Medication Guide), 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 Jacqueline LeeHoffman, Safety Regulatory Project Manager, at (240) 402-8689 or Jacqueline.leehoffman@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology (DG)
Office of Immunology and Inflammation (OII)
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
07/15/2025 11:24:13 AM

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