

NDA 022372-S16

SUPPLEMENT APPROVAL

Braintree Laboratories, Inc.
Attention: Vivian Caballero
Vice President, Regulatory Affairs
100 Grandview Road
Suite 410
Braintree, MA 02184

Dear Vivian Caballero:

Please refer to your supplemental new drug application (sNDA) dated and received, October 7, 2025, received, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Suprep Bowel Prep Kit (sodium sulfate, potassium sulfate and magnesium sulfate) oral solution.

This Prior Approval sNDA provides for revisions to the CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS sections, and addition of a *Postmarketing Experience* subsection in the ADVERSE REACTIONS section of the Prescribing Information (PI) to describe postmarketing cases of serious hypersensitivity reactions.

APPROVAL & LABELING

We have completed our review of this application, as amended. 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:

- Addition of the revision date in the Recent Major Changes section and at the end of the Highlights of the Prescribing Information.
- Revised the subsection number for Recent Major Changes to 5.8.

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 Anum Shami, Regulatory Project Manager, at anum.shami@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
11/18/2025 10:38:04 AM