DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022372/S-003

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Braintree Laboratories, Inc.
Attention: Vivian A. Caballero
Director, Regulatory Affairs
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185

Dear Ms. Caballero:

Please refer to your Supplemental New Drug Application (sNDA) dated May 11, 2011, received May 12, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 11, 2011.

This supplemental new drug application proposes to eliminate the requirement for the approved REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution was originally approved on August 5, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution outweigh its risks.

Therefore, we agree with your proposal and a REMS for SUPREP Bowel Prep Kit (sodium sulfate, potassium sulfate, magnesium sulfate) Oral Solution is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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, call Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

JOYCE A KORVICK
07/06/2011