



NDA 021551/S-016

**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 HalfLyte and Bisacodyl Tablet Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet).

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 HalfLyte and Bisacodyl Tablet Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet) was originally approved on July 16, 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 HalfLyte and Bisacodyl Tablet Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet).

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 HalfLyte and Bisacodyl Tablet

Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet) outweigh its risks.

Therefore, we agree with your proposal, and a REMS for HalfLyte and Bisacodyl Tablet Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed-release tablet) 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