



NDA 021551/S-013

**NOTIFICATION OF
NON-COMPLIANCE WITH PREA**

Braintree Laboratories, Inc.
Attention: Mark Cleveland, Ph.D.
Vice President, New Product Development
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185

Dear Dr. Cleveland:

Please refer to your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) 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), which was approved on July 16, 2010.

The Agency has determined that you have failed to meet the requirements of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment, which was deferred until February 28, 2014.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a **“DEFERRAL EXTENSION REQUESTED”** in your response. We note that you requested a deferral extension on January 2, 2013; however, we have determined that your request does not qualify for an extension.

In accordance with FDASIA, FDA will post this letter and your response on the website located at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm> with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a **“RESPONSE TO PREA NON-COMPLIANCE LETTER.”** To facilitate our review, submit this information to your sNDA with a cross-reference letter to the IND to which your protocol has been submitted. In addition, send a copy of the cover letter to CDER’s Pediatric and Maternal Health Staff.

If you have any questions, call Matthew Scherer, Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology and Inborn Errors
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DONNA J GRIEBEL
03/06/2014