DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-551/S-006

Braintree Laboratories, Inc.
Attention: Mark vB Cleveland, Ph.D.
Vice President, New Product Development
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185-0929

Dear Dr. Cleveland:

Please refer to your supplemental new drug application dated August 28, 2006, received August 29, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HalfLytely® and Bisacodyl Tablets Bowel Prep Kit (PEG-3350, sodium chloride, sodium bicarbonate, and potassium chloride for oral solution and bisacodyl delayed-release tablets).

We acknowledge receipt of your submissions dated November 29, 2006, March 5, March 6, March 16, March 20, March 26, April 18, April 20, May 11, June 7, June 28, June 29, July 2, July 5, September 10, September 11, September 19, and September 24, 2007.

This supplemental new drug application provides for reduction of the bisacodyl dosage from 20mg to 10mg

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted September 11, 2007). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “SPL for approved NDA 21-551/S-006”.

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels (submitted July 2 and July 5, 2007) as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submission Using the eCTD Specifications* (October 2005*)*. Alternatively, you may submit 12 paper copies with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved supplement NDA 21-551/S-006**”. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies from ages birth to 16 years until March 31, 2012.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for cleansing of the colon as a preparation for colonoscopy in pediatric patients ages birth to 16 years.

   Final Report Submission: March 31, 2012

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

We remind you of your postmarketing study commitments in your submission dated September 19, 2007. These commitments are listed below.

2. Description of Commitment

   Conduct a retrospective study comparing and evaluating the occurrence of ischemic colitis following colonoscopy preparations, such as 4 liter polyethylene glycol and electrolyte solutions, to HalfLytely and Bisacodyl Tablets Bowel Prep Kit containing 20mg bisacodyl.

   Protocol Submission: by 12/07
   Study Start: by 2/08
   Final Report Submission: by 6/08

3. Description of Commitment

   Conduct a retrospective study comparing and evaluating the occurrence of ischemic colitis following colonoscopy preparations, such as 4 liter polyethylene glycol and electrolyte solutions, to HalfLytely and Bisacodyl Tablets Bowel Prep Kit containing 10mg bisacodyl. Conduct analyses 6 months, 12 months, 18 months, and 24 months after initial marketing of HalfLytely and Bisacodyl Tablets Bowel Prep Kit containing 10mg bisacodyl.

   Protocol Submission: by 2/08

   Analysis at 6 months after initial marketing:
   First Interim Report Submission: by 8/08

   Analysis at 12 months after initial marketing:
   Second Interim Report Submission: by 2/09

   Analysis at 18 months after initial marketing:
   Third Interim Report Submission: by 8/09

Analysis at 24 months after initial marketing:
Final Report Submission: by 2/10

4. Description of Commitment

Conduct a dose-response study evaluating lower doses of bisacodyl (e.g., 7.5 mg, 5 mg, and/or 2.5 mg) for efficacy and safety in cleansing the colon as a preparation for colonscopy in adults.

Protocol Submission: by 12/07
Study Start: by 6/08
Final Report Submission: by 9/09

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Matt Scherer, M.B.A., Regulatory Project Manager, at (301) 796-2307.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.S.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III

Enclosure

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

/s/

Joyce Korvick
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