DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-698/S-004

Braintree Laboratories, Inc.
Attention: Vivian Caballero
60 Columbian Street
P.O. Box 850929
Braintree, MA 02185

Dear Ms. Caballero:

Please refer to your supplemental new drug application dated February 16, 2001, received February 20, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MiraLax™ (polyethylene glycol 3350, NF Powder).

We acknowledge receipt of your submission dated November 25, 2003. Your submission of November 25, 2003 constituted a complete response to our June 20, 2001 action letter.

This supplemental new drug application provides for the following change: packaging Polyethylene Glycol 3350, NF Powder into a different HDPE container/closure system with generic labeling.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 25, 2003.

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 waiving the pediatric study requirement for this application.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Tanya Clayton, B.S., Regulatory Project Manager, at (301) 827-4005.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Division Director
Division of Gastrointestinal & Coagulation Drug 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/

Robert Justice
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