DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-698/S-009

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

Dear Ms. Caballero:

Please refer to your supplemental new drug application dated February 13, 2004, received February 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MiraLax™ (Polyethylene Glycol 3350, NF Powder for Solution).

We acknowledge receipt of your submission dated August 2, 2004.

This supplemental new drug application provides for the revision of the labeling text from "dissolution in 8 ounces" to "dissolution in 4-8 ounces."

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 and with the minor editorial revision listed below.

The revision dates for the bottle labels must be updated to the current revision date.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling (package insert submitted February 13, 2004, patient package insert submitted February 13, 2004, immediate container and carton labels submitted February 13, 2004 and August 2, 2004). These revisions are terms of the approval of this application.

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 Tanya Clayton, B.S., Regulatory Project Manager, at (301) 827-4005.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy 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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