DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-698/SLR-003

Braintree Laboratories, Inc.
Attention: Mark vB. Cleveland, Ph.D.
P.O. Box 850929
Braintree, MA 02185

Dear Dr. Cleveland:

Please refer to your supplemental new drug application dated November 21, 2000, received November 22, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MiraLax (polyethylene glycol 3350, NF powder).

This supplemental new drug application provides for revising the wording in several sections of the package insert from "Stir the powder in a cup (8 oz.) of water until completely dissolved" to "Stir the powder in a cup (8 oz.) of water, juice, soda, coffee or tea until completely dissolved".

In addition, we refer to the June 18, 2001 and June 20, 2001 telephone conversations between Ms. Vivian Caballero and Ms. Alice Kacuba of this Division in which the following labeling revision was agreed to:

> The only sentence in the second paragraph of the PRECAUTIONS section, "General" subsection will read:
>
> "MiraLax should be administered after being dissolved in approximately 8 ounces of water, juice, soda, coffee or tea."

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 21, 2000 with the agreed upon labeling revision listed above).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-698/SLR-003." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

Although not approvabilities issues:

1. At the time of the next printing of the labeling, change the labeling so that the dosage form is expressed as “powder for solution” to read “polyethylene glycol 3350, NF powder for solution”.

2. Commit to providing samples for the validation of the GPC method for Assay of PEG 3350 described in SOP 110d, as established in the CDER Guideline for Submitting Samples and Analytical Data for Methods Validation (February 1987).

If you have any questions, call Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602.

Sincerely,

{See appended electronic signature page}

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research