DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-011/S-015

Braintree Laboratories, Inc.
Attention: Vivian A. Caballero
Director Regulatory Affairs
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185-0929

Dear Ms. Caballero:

Please refer to your supplemental new drug application dated April 2, 2002, received April 4, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for GoLYTELY® (PEG-3350 and Electrolytes) for Oral Solution.

This "Changes Being Effected" supplemental new drug application provides for revising the ADSVERSE REACTIONS section of the package insert in accordance with the Division's Supplement Request letter dated November 19, 1999.

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.

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.

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}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and 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/

Joyce Korvick
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