DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-797/S-013

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

Dear Caballero:

Please refer to your supplemental new drug application dated December 22, 2000, received December 26, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NuLYTELY® (PEG-3350 , Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution).

We acknowledge receipt of your submission dated March 5, 2003. Your submission of March 5, 2003 constituted a complete response to our April 25, 2001 action letter.

This supplemental new drug application provides for draft labeling revisions, as requested in our April 25, 2001 action letter.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as submitted March 5, 2003.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and immediate container labels) submitted, March 5, 2003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-797/S-013." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, BS, Regulatory Project Manager, at (301) 827-1601.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the Division of Gatrointestinal and Coagulation Drug Products, (HFD-180)
DNDC II, Office of New Drug Chemistry
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/

Liang Zhou

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