DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-976/S-005

Braintree Laboratories, Inc.
Attention: Vivian 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 August 20, 2002, received August 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PhosLo (calcium acetate) Tablets.

This "Changes Being Effected" supplemental new drug application provides for a new **Geriatric Use** section of the label, and adds a sentence to the **Description** section of the label which states, "PhosLo Tablets (calcium acetate) are administered orally for the control of hyperphosphatemia in end stage renal failure."

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 submitted final printed labeling (combined package insert and container label submitted August 20, 2002). 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 Randy Hedin, R.Ph., Senior Regulatory Management Officer, at (301) 827-6392.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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