DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

AUG 1 1999

Mark vB. Cleveland, Ph.D.
Vice President, New Product Development
Braintree Laboratories, Inc.
60 Columbian Street West
P.O. Box 850929
Braintree, MA 02185-0929

RE: NDA 19-976
Phoslo (calcium acetate) tablets
MACMIS ID#7632

Dear Dr. Cleveland:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional material for Phoslo (calcium acetate) that is lacking in fair balance or otherwise misleading. Reference is made to a journal advertisement (TRE 11513) appearing on the back cover of the May 1999 issue of *Contemporary Dialysis and Nephrology*. The publication of this material by Braintree Laboratories, Inc. (Braintree) violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations for the following reasons. DDMAC requests that the use of the above referenced material and those containing similar promotional claims or presentations cease immediately.

Background

Phoslo, a prescription drug product, is approved for the control of hyperphospatemia in end stage renal failure. Phoslo was approved by the Food and Drug Administration (FDA) in 1990.

Failure to Provide Fair Balance

Promotional materials may be false, lacking in fair balance, or otherwise misleading if they fail to present information relating to side effects and contraindications with a

prominence and readability reasonably comparable to the presentation of information relating to effectiveness of the drug. In this journal advertisement, the risk information is presented in unreadable font (very small size), on white background (intertwined with the references), and separated from the bullet-points and bold claims devoted to efficacy by a solid black line. This presentation of risk information is not of comparable prominence to the claims of efficacy and therefore, is in violation of the implementing regulations.

Braintree should immediately cease using this, and all other promotional materials for Phoslo that contain the same or similar claims or presentations. Braintree should submit a written response to DDMAC, on or before August 13, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Braintree should include a list of all promotional materials that were discontinued, and the discontinuation date.

Braintree should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Braintree that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7632 and NDA 19-976.

Sincerely,

/S/

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications