DEPARTMENT OF HEALTH & HUMAN SERVICES

FOI

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

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

APR 01 1999

RE: **NDA 20-698**
MiraLax® (Polyethylene Glycol 3350, NF Powder)
MACMIS ID #~~7551~~ 7751

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 Mirilax® (polyethylene glycol 3350) NF powder disseminated by Braintree Laboratories, Inc. (Braintree) that violate the Federal Food Drug and Cosmetic Act (Act) and its implementing regulations. Reference is made to a material fact sheet, identified as BL 8512-399, that was disseminated at the meeting of the American Pharmaceutical Association held from March 6, 1999, to March 9, 1999, in San Antonio, Texas. DDMAC has reviewed this material and has determined that it promotes Mirilax® in a manner that is false or misleading because it lacks fair balance.

Fair Balance

Promotional materials are false, lacking in fair balance, or otherwise misleading if they fail to present the information relating to contraindications, warnings, precautions, and side effects associated with the use of a drug with a prominence and readibility reasonably comparable to the presentation of information relating to the effectiveness of the drug. In the fact sheet referenced above, Braintree presents several promotional claims for the drug Mirilax. However, the fact sheet fails to present any risk information associated with Mirilax's use. The approved product labeling describes risk information including contraindications, warnings, precautions, and adverse reactions associated with Mirilax's use. The fact sheet you disseminated is lacking in fair balance because it fails to identify these risks.

Failure to Submit Post-Marketing Reports

We note that this promotional material was disseminated on March 6, 1999. However, you failed to submit this fact sheet to FDA. Such material is required to be submitted at the time of its first use under the post-marketing reporting requirements (21 C.F.R. 314.81(b)(3)(i)).

Conclusions and Requested Actions

Braintree should immediately cease distribution of this and other similar promotional materials for Mirilax that contain the same or similar claims without balancing risk information. Braintree should submit a written response to DDMAC on or before April 14, 1999, describing its intent and plans to comply with the above.

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 # 7751 and NDA 20-698.

Sincerely,

/S/

John C. Markow, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications