DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFD-19 Chap

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

FEB 24 1997

Mr. Richard Deer
President
BDI Pharmaceuticals
Division of Body Dynamics, Inc..
2518 N. Arlington
Indianapolis, Indiana 46201

Ref: 97-HFD-312-02

Dear Mr. Deer:

This is in reference to "Mini Thin" tablets distributed by your firm. Each tablet contains 25 mg. ephedrine hydrochloride and 100 mg. guaifenesin. The "statement of identity" and "indications" portions of the label state that the product is a bronchodilator and an expectorant.

The trade name of your product, "Mini Thin," suggests that the product is intended to aid in "weight loss," an unapproved use. The only OTC drug ingredients the FDA permits to be marketed at this time for weight loss claims, under limited conditions, are phenylpropanolamine hydrochloride and benzocaine. Because "Mini Thin" tablets are intended for weight loss purposes, it must comply with agency policy on OTC weight loss drugs. Since ephedrine hydrochloride and guaifenesin are not included in the ingredients permitted to be marketed OTC for weight loss, we consider "Mini Thin" tablets to be a "new drug" (section 201(p) of the Federal Food, Drug, and Cosmetic Act (the Act)), which may not be legally marketed in the United States as it is not the subject of an approved New Drug Application (section 505).

We continue to receive reports that the product is being used for weight loss. The FDA believes that there are serious health risks inherent in the promotion of ephedrine for weight loss use. Significant adverse reactions linked to the use of "Mini Thin" tablets as a weight loss drug have been reported. It is our position that the trade name "Mini Thin" must be changed in order to ensure that the product is not intended/promoted for the unacceptable weight loss use.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857, Attention: Robert A. Eshelman, Compliance Officer.

If you choose to correct the trade name violation noted above, and continue to market the combination product as a bronchodilator and expectorant, you will need to revise the formulation. The acceptable dosage for guaifenesin as an expectorant is 200 mg to 400 mg every 4 hours (21 CFR 341). Additionally, you must ensure that the labeling conforms with the requirements of 21 CFR 341 in all respects.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and
Nonprescription Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research