



VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-00-43

March 29, 2000

Gary A. Shawkey
Founding Director
Bodies Best, Inc.
13114 Hazelcrest Street
Spring Hill, Florida 34609

Dear Mr. Shawkey:

This letter is in reference to your firm's marketing, labeling (including promotional materials), and distribution of your product known as "HGH Support".

Promotional literature (labeling) accompanying "HGH Support" caused your product to be a drug. This was brought to your attention during the inspection of December 14, 1999. Despite your assurances that offending statements and claims would be removed, the promotional literature, "Manual for Success", and your Internet website continue to contain stated or implied disease claims such as "... resistance to infection; faster injury healing, including wounds and fractures ... reversal of osteoporosis; decrease of LDL cholesterol ' the bad kind' ... reduction of depression ... reduction of high blood pressure ...".

Based on the above claims, this product is a drug [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and a "new drug" [section 201(p) of the Act]. Therefore, it may not be marketed in the United States without an approved New Drug Application (NDA) [section 505(a) of the Act].

This drug is also misbranded [section 502(f)(1) of the Act] because the labeling fails to bear adequate directions for use. The labeling is false and misleading as it suggests the product is safe and effective for its intended uses when, in fact, this has not been established [section 502(a) of the Act].

In addition, your promotional literature (labeling) for "Bodies Best Weight Loss and Energy Booster" makes therapeutic claims of being "an antibiotic cleanse" that implies properties of treating disease.

Gary A. Shawkey
Page 2
March 29, 2000

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

You should reply to Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,



Marie A. Urban
Acting Director
Florida District