



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m2374n
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-33

February 4, 1999

Mr. Randal G. Park
President
Natural Bodylines, Inc.
11 Riverside Drive
Cocoa, Florida 32922

Dear Mr. Park:

This letter is in reference to your firm's marketing and distribution of the product, Natural TrimPatch. Labeling for Natural TrimPatch claims that this product will deliver its active ingredients by the transdermal route of administration. The labeling also claims that this product will suppress appetite, reduce cravings, and cause weight loss. Such claims cause the product to be a drug [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)].

In addition, transdermal delivery systems are not recognized by the homeopathic community as valid homeopathic dosage forms. In 1989, the Agency made a determination that transdermal delivery systems are not homeopathic and that transdermal patches are new drugs based on the newness of the delivery system [Title 21, Code of Federal Regulations (21 CFR), section 310.3].

Natural TrimPatch is a "new drug" [section 201(p) of the Act]. Therefore, it may not be legally marketed in this country without an approved New Drug Application [section 505(a) of the Act].

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

Mr. Randal G. Park

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This letter is not intended to be an all inclusive review of labeling and products your firm may market. 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 promptly correct these 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 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, including an explanation of each step being taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the attention of Martin E. Katz, Compliance Officer, Florida District, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in cursive script, appearing to read "Douglas D. Tolen".

Douglas D. Tolen
Director, Florida District