



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Atlanta District Office
60 Eighth Street N.E.
Atlanta, GA 30309

Telephone: 404-253-1161
FAX: 404-253-1202

March 6, 2002

VIA FEDERAL EXPRESS

WARNING LETTER
(02-ATL-22)

Jared R. Wheat, President
Hi-Tech Pharmaceuticals
5675 Jimmy Carter Blvd., Suite 720
Norcross, GA 30071

Dear Mr. Wheat:

This letter is in reference to your firm's marketing and distribution of Metanabol. Labeling for this product contains therapeutic claims which cause the product to be a drug (section 201(g)(1)(B)) of the Federal Food, Drug, and Cosmetic Act (the Act). Labeling is not limited to the immediate product container, but, as defined in section 201(m) of the Act, includes all promotional material you distribute in connection with your product.

Your reorder form for Metanabol states, "Metanabol is intended to support the erectile function of all men who have experienced ANY degradation in erectile health, and is virtually safe for ALL people, including: diabetics, people with hypertension, prostate dysfunction, etc..." This statement causes your Metanabol product to be a drug as defined in section 201(g)(1)(B) of the Act because it implies that the product is intended to treat erectile dysfunction that is a consequence of the listed diseases. Because we are unaware of any evidence that this product is generally recognized as safe and effective when used as labeled, it also is a new drug as defined under section 201(p) of the Act. Under section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

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

This letter is not intended to be an all inclusive review of all 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.

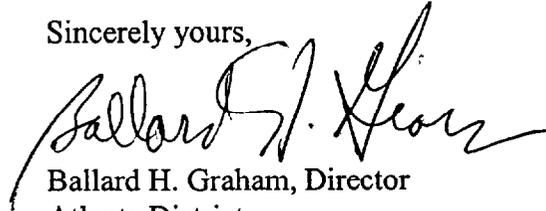
We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without

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 identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed with 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Sheryl R. Cruse at the above letterhead address.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District