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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-79

August 19, 1997

William S. Huang, M.D.
Health Awareness Medical Center
2905 Lakeview Drive
Fern Park, Florida 32730

Dear Dr. Huang:

An inspection of your firm on April 9, 1997, by FDA Investigator Jose R. Rodriguez revealed that you have promoted the products, FLORITABS (also labeled as FLORITBAS) and FLORITAB Plus, for the treatment of hypertension, and have distributed these products to your patients as well as to at least one retail outlet.

Analysis of these products revealed the presence of the following undeclared prescription drug ingredients: promethazine, chlordiazepoxide, and chloroquine. The inclusion of drug active ingredients and the disease treatment claims cause these products to be drugs as defined under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

These drugs are misbranded as described in Sections 502 and 503 of the Act in the following aspects:

502(a), in that their labels are false and misleading because they fail to list two therapeutically significant ingredients, promethazine and chlordiazepoxide;

502(b), in that their labels fail to bear the name and address of the manufacturer, packer, or distributor;

502(d), because they contain the drug ingredient, chlordiazepoxide, which has been found to be habit forming and their labels fail to bear the statement "Warning--May be Habit Forming";

502(f)(1) and (2), because their labels fail to bear adequate directions for use for the condition for which they are offered and because their labels fail to bear adequate warnings against unsafe dosage, methods, or duration of administration;

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502(f)(1) of the Act, since the conditions for which it is intended are not amenable to self-diagnosis and treatment by laypersons (21 CFR 201.5). Adequate directions for use cannot be written under which a layman can use this drug safely; and,

503(b)(4), because the product fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription" [21 CFR 201.100(b)(1)].

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 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. Please also include an explanation of each step being taken to identify and assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, 7200 Lake Ellenor Drive, Ste. 120, Orlando, Florida 32809, Attn: Martin E. Katz, Compliance Officer, (407) 648-6823, ext. 262.

Sincerely,



Douglas D. Tolen
Director, Florida District