HFD-205

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 29 1997

WARNING LETTER

Mr. Perry Hitt
Hit Products, Incorporated
c/o Riverdale Tobacco Shop
6725 44th Avenue
Hyattsville, Maryland 20782

Ref. No: 97-HFD-310-04

Dear Mr. Hitt:

This letter notifies you that your drug product, "X TABLETS," is in violation of the Federal Food, Drug, and Cosmetic Act (the FFDCA). The product is labeled as containing "High potency concentrates of fresh ginko biloba, siberian wuchaseng, spirulina, South American guarana, and Ma Huang."

"X TABLETS" are identified in promotional material as "The World's most powerful ecstasy alternative," "Pleasurable stimulation of the senses... a real body and cerebral experience," "Tingling sensations, positive vibes, & poweful rush..." These street drug alternative claims, and the use of the name "X TABLETS," do not fall within the scope of claims permitted for dietary supplements.

As labeled, "X TABLETS" is a drug as described in §201(g) of the FFDCA and a "new drug" as described in §201(p) which may not be legally marketed in the United States without an approved New Drug Application. In addition, it is misbranded as described in §502(f)(1) of the FFDCA because its labeling fails to bear adequate directions for the uses for which it is being promoted.

The claims and name indicate that "X TABLETS" is offered for abuse and misuse purposes. As such, there is no legitimate drug use for this product and its continued marketing is illegal.

We request you take prompt action to correct these violations. Failure to promptly correct them may result in enforcement action being initiated by the Food and Drug Administration without further notice. The FFDCA provides for seizure of illegal products (§304) and for injunction (§302) against the manufacture and/or distribution of illegal products.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations.

Your reply should be sent to the Division of Labeling and Nonprescription Drug Compliance, HFD-310, Food and Drug Administration, 7520 Standish Place, Rockville, MD 20855.

Sincerely yours,

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