HFD-205

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 29 1997

WARNING LETTER

Mr. Robert Hillard
International Oddities
4731 Clark Avenue
Long Beach, California 90808

Ref. No: 97-HFD-310-03

Dear Mr. Hillard:

This letter notifies you that your drug product, "Herbal Advanced Formula Hextasy," is in violation of the Federal Food, Drug, and Cosmetic Act (the FFDCA). The product is labeled as containing "A superior, synergistically re-synthesized herbal supplement Ingredients - Muira Pauma, Ma Huang, Fo-Ti, Guarana, Catuba, Cola Nut, Ginko Biloba, Rou Gui, Chinese Green Tea, Suma, Gotu Cola, Ginseng."

"Herbal Advanced Formula Hextasy" is identified in promotional material as "Absolutely the BEST of all the extacy alternatives (Guaranteed) . . . But none have the Super Happy Feelings, Cerebral Sensory Expansion, Extreme Euphoria, Mood Elevation, Tingling & Sexual Sensations of Hextasy!! 'Effects came on immediately - lasted 5 hours with no burn out. Amazing' 'You've done it - Pure euphoric joy in a pill. Thanks' 'Legal or not - this is the greatest thing I've tried in a long time.'" These street drug alternative claims, and the use of the name "Herbal Advanced Formula Hextasy" do not fall within the scope of claims permitted for dietary supplements.

As labeled, "Herbal Advanced Formula Hextasy" 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 (NDA). 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 "Herbal Advanced Formula Hextasy" 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